The use of imaging in the diagnosis of lower urinary tract disorders and pelvic organ prolapse in women

a thesis by

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"It is the mark of an educated mind to be able to entertain a thought without accepting it."

Aristotle, 384 BC – 322 BC
ABSTRACT

The wide range of pelvic floor disorders is often difficult to assess thoroughly based on clinical examination alone. The assessment of patients with pelvic floor dysfunction necessitates a combination of clinical skills and adjunct investigations, including detailed imaging. A variety of static and dynamic imaging modalities are currently available in the field of urogynaecology, however their role in identifying the structural and functional causes of pelvic floor disorders remains equivocal. This thesis poses the null hypothesis that imaging techniques, namely three- and four-dimensional (3D/4D) ultrasound and spiral computed tomography (CT) have no role in clinical urogynaecology. The hypothesis would be false if such imaging techniques yield measurable differences in anatomical and functional indices of the lower urinary tract and pelvic floor.

The interaction between the vagina and its supportive structures, as well as their behaviour under the mechanical load of increased abdominal pressure can be modelled as a biomechanical system; In the present thesis the changes in dimensions of the levator ani muscle (LAM) in women with pelvic floor dysfunction (PFD) were measured in vivo, under progressively increased abdominal pressure, with the use of translabial ultrasound imaging demonstrating that real-time in vivo study of the deformation of the pelvic floor with 3D/4D translabial ultrasound is feasible and reliable.

The reliability of translabial 3D ultrasound imaging of the urethral sphincter in non-pregnant, nulliparous and asymptomatic women was also assessed. Very good to excellent inter- and intra-observer agreement was demonstrated
proving the reproducibility of a method which doesn’t carry the inherent limitations of the endovaginal and transanal approach.

The potential structural differences in urethral sphincter and pelvic floor between white and black women attributing to the different prevalence of stress urinary incontinence in the two racial groups were assessed with 3D ultrasound imaging. Young nulliparous black women were found to have significantly larger urethral rhabdosphincter muscle (RS) and wider levator hiatus than their white counterparts.

The prevalence of pubovisceral muscle avulsion, as one of the proposed types of pelvic floor trauma during childbirth, was calculated in a general gynaecological cohort with the use of spiral CT of the pelvis. A significantly lower prevalence of pubovisceral muscle avulsion was found in the studied group in comparison to previous reports, which underlines the great variability in depiction of LAM morphometry between different imaging modalities.

In chapter 8, the additive value of 3D/4D pelvic floor ultrasound in evaluating the postoperative outcome of surgical prolapse repair is studied through a randomised control trial in which two different surgical techniques for repairing posterior wall prolapse are compared.

At the end of this thesis, suggestions for further research into the value of new imaging modalities in enhancing clinical assessment of women with pelvic floor dysfunction are made.
DECLARATION

The work contained in this thesis was carried out between August 2009 and May 2012 in the Department of Urogynaecology, St Mary’s Hospital, Imperial College Healthcare NHS Trust.

All included studies had received approval from the local Research Ethics Committee and participants gave informed consent in writing. All the work in this thesis is my own and none of this data forms part of any other thesis.

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Alexandros Derpapas, MD
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The work presented in this thesis is the result of the input of many, but first and foremost of the women who participated in these research studies. I would like to thank all of them for their time, contribution and commitment in this long journey.

I would like to thank Mr Vik Khullar for providing the incentive, support and encouragement throughout my time as a research fellow at St Mary’s Hospital, Imperial College Healthcare NHS Trust London, and his guidance as a whole in my career in the Academia. I am very fortunate in having worked with such an inspirational mentor. I remain indebted to him.

This work would not have been completed without the support of the Urogynaecology team at St Mary’s Hospital. For nearly three years they have stood by me in persevering with data collection and utilisation of resources inside and outside the department. In particular, I would like to thank Ms Caroline Hendricken, Urogynecology Specialist Nurse, for supporting me with the clinical work whenever I would dive in the research waters too deep! My gratitude also extends to Mr Ruwan Fernando, Professor Lesley Regan and Mr Omar Faiz for looking through my thesis and providing me with their invaluable comments.

Behind this thesis there is the unfailing support of my mother Dora, my father Kyriakos and my brother Michael, who have been an enormous source of encouragement to achieve this goal.
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<td>ARA</td>
<td>Anorectal Angle</td>
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<tr>
<td>ATLA</td>
<td>Arcus Tendineus Levator Ani</td>
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<tr>
<td>ATFP</td>
<td>Arcus Tendineus Fascia Pelvis</td>
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<tr>
<td>BWT</td>
<td>Bladder Wall Thickness</td>
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<tr>
<td>DO</td>
<td>Detrusor Overactivity</td>
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<tr>
<td>EAS</td>
<td>External Anal Sphincter</td>
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<td>FEP</td>
<td>Fascial and Vaginal Epithelial Plication</td>
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<td>FI</td>
<td>Faecal Incontinence</td>
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<tr>
<td>GH</td>
<td>Genital (Urogenital) Hiatus</td>
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<tr>
<td>IAS</td>
<td>Internal Anal Sphincter</td>
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<tr>
<td>ICC</td>
<td>Intra-class Correlation Coefficient</td>
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<td>ICS</td>
<td>International Continence Society</td>
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<td>IUGA</td>
<td>International Urogynecological Association</td>
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<tr>
<td>LAM</td>
<td>Levator Ani Muscle</td>
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<tr>
<td>LH</td>
<td>Levator Hiatus</td>
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<td>LSG</td>
<td>Levator Symphysis Gap</td>
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<tr>
<td>LUTS</td>
<td>Lower Urinary Tract Incontinence</td>
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<tr>
<td>MoD</td>
<td>Mode of Delivery</td>
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<tr>
<td>MPL</td>
<td>Mid-Pubic Line</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<td>MSL</td>
<td>Maximum Urethral Sphincter Length</td>
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<tr>
<td>MUCP</td>
<td>Maximum Urethral Closure Pressure</td>
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<tr>
<td>MUL</td>
<td>Maximum Urethral Length</td>
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<td>Pabd</td>
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<td>PFD</td>
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<td>POPQ</td>
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<td>PR</td>
<td>Puborectalis Muscle</td>
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<td>PM</td>
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<td>PVM</td>
<td>Pubovaginalis (Pubovaginal) Muscle</td>
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<tr>
<td>PUM</td>
<td>Pubourethralis (Pubourethral) Muscle</td>
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<tr>
<td>RS</td>
<td>Rhabdosphincter Muscle</td>
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<td>RSV</td>
<td>Rhabdosphincter Muscle Volume</td>
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<td>RVS</td>
<td>Rectovaginal Septum</td>
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<td>SUI</td>
<td>Stress Urinary Incontinence</td>
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<tr>
<td>TSV</td>
<td>Total Urethral Sphincter Volume</td>
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<tr>
<td>UI</td>
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<tr>
<td>UUI</td>
<td>Urgency Urinary Incontinence</td>
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<tr>
<td>SPC</td>
<td>Standard posterior colpoperineorrhaphy</td>
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<tr>
<td>UDS</td>
<td>Urodynamic investigation</td>
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<tr>
<td>VCU</td>
<td>Video-cystourethrography</td>
</tr>
<tr>
<td>VCUG</td>
<td>Voiding Cystourethrography</td>
</tr>
<tr>
<td>VLPP</td>
<td>Valsalva Leak Point Pressure</td>
</tr>
<tr>
<td>VWT</td>
<td>Vaginal Wall Thickness</td>
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The following publications have resulted from this thesis:

**Pelvic floor ultrasonography in assessing the difference in anatomical outcomes between two techniques for posterior wall prolapse repair: a randomised controlled trial**

**Real-time in vivo assessment of levator ani muscle deformation in women**

**Prevalence of pubovisceral muscle avulsion in a general gynecology cohort: A computed tomography (CT) study**

**Intraobserver and interobserver reliability of the three-dimensional ultrasound imaging of female urethral sphincter using a translabial technique**

**Racial differences in female urethral morphology and levator hiatal dimensions: an ultrasound study**

**Imaging in urogynaecology**
PRESENTATIONS

The following presentations have resulted from studies included in this thesis:

1. Levator ani muscle avulsion: what is the true prevalence? (EUGA 2013)
2. Clinical and ultrasonographic assessment of two different surgical techniques for posterior vaginal wall repair: a randomised control trial (IUGA 2013)
3. Does 3d/4d ultrasound imaging of the pelvic floor add valuable information to the assessment of women with pelvic organ prolapse? (IUGA 2011)
4. Real time biomechanics of the pelvic floor (ICS 2011)
5. The intra and inter-observer reliability of the three-dimensional ultrasound imaging of female urethral sphincter (IUGA 2011)
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**Overall null hypothesis**

Imaging techniques, namely three- and four-dimensional (3D/4D) ultrasound and spiral computed tomography (CT) of the pelvic floor have no role in clinical urogynaecology. The hypothesis would be false if such imaging techniques yield measurable differences in anatomical and functional indices of the lower urinary tract and pelvic floor.
CHAPTER 1

Setting
Chapter 1: Setting

This thesis is a result of combined research projects undertaken in the Department of Urogynaecology, at St Mary’s Hospital, Imperial College Healthcare NHS Trust, between August 2009 and May 2012.

The Department of Urogynaecology at St Mary’s Hospital is a tertiary referral centre led by Mr Vik Khullar, Reader in Urogynaecology. The Department accepts referrals from various parts of the U.K and often from abroad. The team at the time this thesis was conducted consisted of two Consultant Urogynaecologists, one subspecialty trainee in Urogynaecology, two clinical research fellows (of which I was one) and a specialist nurse. A comprehensive service is offered to the urogynaecological patients referred to the Department. Conventional cystometrogram, video-cystourethrogram, urethral pressure studies and ambulatory urodynamics are offered as part of the diagnostic work up for pelvic floor disorders. Clinical evaluation of patients with pelvic organ prolapse or/and urinary incontinence is supplemented by objective quantification of prolapse with POP-Q as well as patients self-completed standardised disease specific questionnaires. In addition, magnetic resonance imaging (MRI) of the pelvic floor is utilised when appropriate to enhance clinical assessment of patients with a complex history of chronic pelvic pain, defaecatory problems or previous mesh augmented surgical procedures. Two-dimensional ultrasonography is used both in clinics and the urodynamic suite to allow for further assessment of voiding dysfunction as well as aid the diagnosis of women with overactive bladder (OAB) symptoms and inconclusive urodynamic investigations.

A weekly pelvic floor clinic is also run jointly with the Colorectal surgeons in which women suffering from postpartum pelvic floor disorders are seen.
Endoanal ultrasound of the anal sphincter muscle complex and anal sphincter manometry is routinely offered to women who have sustained third and fourth degree perineal tears, whereas more complex cases are investigated by MRI defaecating proctograms.

The Urogynaecology team is working closely with various medical specialists and allied healthcare professionals. Weekly multidisciplinary meetings are held in the Department with the presence of women’s pelvic floor physiotherapists to discuss management of complex cases and streamline follow ups. Urologists, Colorectal Surgeons, Neurologists, Care of the Elderly Specialists and Pain Team Consultants are often consulted and actively involved in the management of women with complex and debilitating conditions which require holistic approach and long term care.

The Department of Urogynaecology runs a very active research programme. Clinical research fellows are co-investigators in numerous clinical trials and running their own original research projects assisted by visiting research fellows and medical students conducting MSc projects. There is a high output of publications in peer reviewed journals and presentations in important national and international scientific meetings.
CHAPTER 2

The anatomy of the female pelvic floor and lower urinary tract
Chapter 2: The anatomy of the female pelvic floor and lower urinary tract

A. Pelvic Floor

The pelvic floor is a complex system, with passive and active components that provide pelvic support, maintain continence, and coordinate relaxation during urination and defecation. The term pelvic floor refers to all of the muscles, the connective tissue, and the organs that fill the pelvic cavity. The pelvic floor muscles form a diaphragm that spans the pelvic cavity. Its fibres have a U shape configuration surrounding the urogenital hiatus, an arrangement that allows their constant activity to close the hiatus, providing support for the pelvic and abdominal organs. The levator ani muscle (LAM) consists of three distinct subunits (Terminologia anatomica): the pubovisceral muscle complex complex (further divided in pubovaginal, puboanal and puboperineal muscles), the puborectalis and iliococcygeus muscles (Margulies RU et al. 2007).

These parts of the levator ani muscle form three different regions of the pelvic floor; the first region is that formed by the iliococcygeus muscle that forms a horizontal sheath spanning the gap between the two pelvic side walls near the sacrum; the second region includes the pubovisceral muscle consisted of fibres that arise from the inferior aspect of the pubic ramus bilaterally and project to the walls of the pelvic organs and the perineal body maintaining the formation of the urogenital hiatus, and finally the third region which is formed by the puborectalis muscle whose fibres form a sling around the rectum, just cephalad to the anal sphincter (Figure 2.1).

The normal configuration of the levator ani muscle holds the urogenital hiatus closed against the opening action of intra-abdominal pressure. The muscle exerts a force in a ventrocephalic direction so as to allow compression of the
rectum, vagina, and urethra from back to front against the intra-abdominal pressure. In the upright position, the vaginal closure force exerted by the levator ani muscle is 92% greater than in the supine posture (Hodges PW et al. 2007).

The endopelvic fascia is the connective tissue within the pelvic floor, which attaches and suspends the pelvic viscera to the pelvic sidewalls. It is a continuous sheet from the level of the uterine artery to the attachment of the vagina to the levator ani muscle. Different portions of this continuous sheet are given specific names as the consistency of this fascia and its attachments vary. The portion of the endopelvic fascia attached to the uterus is called the parametrium and comprises the uterosacral and cardinal ligaments. The vaginal attachment of the endopelvic fascia is called the paracolpium. Laterally the endopelvic fascia is attached to the arcus tendineus fascia pelvis (ATFP), commonly referred to as the “white line”, which is a condensation of this fascia. The ATFP is attached anteriorly to the caudal aspect of the pubic bone 1cm lateral and 1cm above the lower border of the pubic symphysis, and posteriorly to the medial surface of the ischial spines. Its anterior portion lies on the inner surface of the levator ani muscles and posteriorly it fuses with the tendineous line of origin of the levator ani muscles, the arcus tendineus levator ani (ATLA).

The cardinal and uterosacral ligaments are not actual ligaments as their structure is not similar to other true ligaments, such as in the knee joint, for example. The cardinal ligaments consist of blood vessels, nerves and fibrous connective tissue. The uterosacral ligaments are composed of smooth muscle not seen in the cardinal ligament and they are attached to the dorsal surface of the cervix.
Figure 2.1 Anatomy of pelvic floor
B. Vaginal support

The normal support of the vagina was described by John DeLancey in his paper on the anatomy of vaginal vault eversion in 1992. He describes support of the vagina at three levels, now referred to as DeLancey levels (Figure 2.2).

Level I consists of the uterosacral and cardinal ligaments continuous with the paracolpium. They support the cervix and upper part of the vagina originating from a broad area overlying the piriformis muscle, the lateral sacrum and the area over the sacroiliac joints. In the upright position these level I supports are oriented in the vertical direction and they suspend the uterus, cervix and upper portion of the vagina posteriorly over the levator ani muscles.

Level II consists of smooth muscle, collagen and elastin and attaches the vagina laterally to the ATFP and levator ani muscle. This attachment stretches the vagina transversely between the bladder and rectum. This layer is not distinct from the vagina and is a continuation of the vaginal wall and its attachments to the pelvic side wall. The anterior vaginal wall with the fascia is termed the “pubocervical fascia” and it supports the bladder. Similarly the posterior vaginal wall fascia is often referred to as the rectovaginal fascia and it supports the rectum from bulging forwards into the vagina forming a rectocele.

Level III is the level in the lower one third of the vagina where no paracolpium exists. The vagina is directly attached to the urethra anteriorly, the perineal body posteriorly and the levator ani muscles laterally. In this part, movement of the vagina is not independent of its attachments.
C. The urethra and its supports

The urethra is a complex tubular structure which plays an important role in urinary continence. It holds the urine in the bladder even during periods of increased abdominal pressure. The function of the urethra is dependent on its anatomical components and supporting structures.

The wall of the urethra comprises an inner mucous membrane, which lines the epithelium in continuation with the bladder epithelium and an outer muscle coat. The muscle coat in turn consists of an outer sleeve of circular striated muscle (rhabdosphincter muscle) and an inner, then, coat of circular smooth muscle fibres and a thicker innermost coat of longitudinal smooth muscle.

The striated urogenital sphincter is part of the pelvic floor. It lies just above the perineal membrane and is composed of the compressor urethrae, urethrovaginal sphincter and the sphincter urethrae. The fibres of the sphincter urethrae are placed in a circular fashion. The urethrovaginal sphincter encircles the vaginal wall and the compressor urethrae extends along the inferior pubic ramus above the perineal membrane.

The urethral smooth muscle is a continuation of the smooth muscle in the trigone and the detrusor and is separate from the striated urogenital sphincter. It has an inner longitudinal layer and a thin outer circular layer as mentioned previously. The circular layer plays a role in constricting the urethra and the longitudinal layer helps to shorten and open the urethra during voiding.
Figure 2.2 Levels of vaginal support (DeLancey JO 1992)
The proximal urethra is supported by the endopelvic fascia and the anterior vaginal wall, which acts like a hammock and attaches it to the ATFP and the levator ani muscle (Porges et al 1960). The proximal urethra musculature is composed of slow –twitch muscle fibres, which maintain a constant resting tone. In addition, the sphincter tone can be further increased by voluntary contraction to maintain continence. In the distal portion of the urethra this muscle compresses the urethra from above and in the proximal portion it constricts the urethra.

Within the urethra is a vascular plexus which has a network of arteriovenous anastomoses. The flow of blood into the large venules can be controlled to inflate or deflate them. This helps to form a water tight seal of the mucosal surface. These appear to be hormone sensitive (Williams AB et al 2001) and may explain the increase in incontinence after menopause and also improvement with local oestrogen supplementation. The adult female urethral is 20-35 mm long and around 6 mm in diameter in nulliparous women (Umek WH et al 2003). The bladder neck extends to 15mm below the bladder base. The urogenital sphincter is found between 5-25mm below the bladder base. The proximal part of the urogenital sphincter contains the sphincter urethrae. The distal part from 15-25mm below the bladder base contains the compressor urethrae and urethrovaginal sphincter muscles. In the perineal membrane region the urethra is fused with the perineal membrane and surrounding structures. The distal urethra is identified caudal to the perineal membrane.

In the upper third the urethra is separate from the vagina, but in the lower part it is fused with the anterior vaginal wall. The support of the urethra depends on the attachments of the vagina and the periurethral tissues to the muscles and fascia of the pelvic side wall. The pubourethral ligaments are attachments
of the periurethral tissues to the pubic bone. They are continuous with the connective tissue of the perineal membrane. In addition, a separate structure called the pubovesical ligament is providing extra support to the urethra. This is a structure composed of muscular and fibrous elements. The muscular element is derived from an extension of the detrusor muscle. This ligament runs in front of the vesical neck and proximal urethra and plays a role in opening the bladder neck during micturition (DeLancey JOL et al. 1989).
CHAPTER 3

Imaging in Urogynaecology
Chapter 3: Imaging in Urogynaecology

The wide range of pelvic floor disorders are often difficult to assess completely based on clinical examination alone. Understanding of the physiology of pelvic floor dysfunction integrated with multimodal imaging is the key to a holistic approach of such disorders. Due to the high complexity of pelvic floor functional anatomy, new imaging techniques have been introduced to enhance clinicians’ understanding of incontinence and prolapse, which could provide useful information for better management of these disorders. Both static and functional imaging modalities of the pelvic floor have recently been employed in the modern management of pelvic floor disorders.

3.1 Static imaging

3.1.1 Endoanal Ultrasound

The incidence of anal sphincter defects following vaginal delivery detected by endoanal ultrasonography is 30% for primiparae and 9% in multiparae (Oberwalder M et al. 2003). Evaluation of internal anal sphincter (IAS) and external anal sphincter (EAS) with endoanal ultrasound is the gold standard in investigating patients with obstetric anal sphincter injuries and anal incontinence. High resolution scanning endopores are sensitive in detecting sphincter damage due to their enhanced spatial resolution and reduced diameter that limits patients’ discomfort. The lubricated probe is inserted in the anus with the woman lying in a lateral position and images are taken in the axial plane; however, with the advent of three-dimensional technology, images can be also taken and analysed in the sagittal and coronal plane (Christensen AF et al. 2005).

Endoanal ultrasound requires operator experience to facilitate the correct interpretation of the images. The sphincter complex produces different
reflectivity of the various tissues, hence providing a typical image of the subepithelial tissue being exactly adjacent to the probe and the internal anal sphincter seen as an outer hypoechogenic (black) circle ring. On the outside of the internal anal sphincter, a longitudinal layer can be seen, which is formed by an extension of the longitudinal smooth muscle of the rectum and fibro-elastic tissue of the endopelvic fascia. The external anal sphincter is visualised as a hyperechogenic circular structure on the outermost aspect and its thickness varies according to the level of the anal canal (Thakar R, Sultan AH, 2004).

More specifically, the upper anal canal is identified by a hyperechoic horseshoe sling of the puborectalis muscle posteriorly and the absence of the EAS in the midline anteriorly. The mid-anal canal level, which includes deep and superficial parts of the anal sphincter complex, is identified by the completion of the EAS ring anteriorly in combination with the maximum IAS thickness (Fig. 3.1.1). The lower canal level is defined as that immediately caudal to the termination of the IAS and comprises only the subcutaneous EAS.

The IAS thickens with age and is abnormally thickened in women with rectal prolapse and intussusceptions (Kamm MA et al. 1991). EAS bulk and thickness is not as well delineated with endoanal ultrasound. Magnetic resonance imaging (MRI) has been found to be better in visualising the fat replacement of the muscle as a result of atrophy (Cazemier M et al. 2006).

The most common clinical indication for endoanal ultrasound is the assessment of sphincter integrity following obstetric trauma. Sphincter damage may occur as a result of perineal trauma or extension of an episiotomy during childbirth and almost invariably involves the anterior part of the sphincter. Fibrotic tissue replaces the muscle fibres as part of the healing process following a repair, and this appears as a low echogenic band on
ultrasound. Perineal tears may involve EAS and IAS and if clinically undetected will result in muscle defects (Figure 3.1.2).
Figure 3.1.1 Normal anatomy of anal sphincter complex at the deep external anal sphincter level

(IAS internal anal sphincter, EAS external anal sphincter)

Figure 3.1.2 A persistent defect of the anterior external (white arrows) and internal anal (black arrows) sphincter
3.1.2 Pelvic floor ultrasound

Pelvic floor ultrasound has recently enhanced imaging of pelvic floor anatomy. Standard requirements for two-dimensional translabial/transperineal ultrasound of the pelvic floor include a B-mode ultrasound scanner with cine-loop function and a 3.5–6 MHz curved array transducer. Although currently used mainly in specialist urogynaecology centres, pelvic floor ultrasound could be used in any outpatient clinical setting without causing discomfort to the patient. Three-dimensional pelvic floor ultrasound provides both static and dynamic imaging allowing assessment of the anatomy and function of the different compartments. Three-dimensional ultrasound allows unrestricted number of images to be obtained through volume at any angle to the ultrasound beam. Additionally it allows accurate volume measurements to be obtained either on-line or off-line with the use of dedicated software.

With respect to the technique used, the curved array ultrasound probe is placed on the perineum after being covered with non-powdered glove or plastic wrap, with the patient lying in the dorsal lithotomy position with the hips flexed and slightly abducted. Alternatively, the technique can be performed with the woman in the standing position. The patient must empty her bladder prior to voiding, leaving ideally a residual of no more than 30 ml. The quality of the image is enhanced by spreading of the labia and reflection of ultrasound waves on tissue of adequate hydration; images are of often better quality in pregnant women and less clear in postmenopausal women (Dietz HP 2010).

The standard midsagittal view includes the symphysis pubis anteriorly with the urethra and bladder neck laying immediately dorsally, the vagina and cervix medially and the rectum and anal canal visualised posteriorly. Further
posteriorly to the anorectal junction, the central portion of the levator plate is seen as a hyperechoic structure. In the case of three-dimensional (3D) pelvic floor ultrasound, parasagittal or/and axial views often yield additional information, i.e. confirming urethral integrity, enabling assessment of the puborectalis muscle and depicting mesh implants and slings. Problems with obtaining a good view of the pelvis can be secondary to vaginal prolapse casting shadows, the pubic bone making a shadow and a full rectum, particularly in association with a rectocele obscuring the posterior compartment. Visualisation of the apex can also be challenging when such conditions are met. Static three-dimensional images of the pelvic floor can be obtained in three planes: sagittal, coronal and axial, whereas rendered volume images can provide an enhanced view of the soft tissues, especially the levator ani muscle complex (Figure 3.1.3).

Pelvic floor ultrasound can be used to depict the anatomy in all three vaginal compartments. With regards to the anterior vaginal compartment, ultrasound can help determine the position of the bladder neck as well as its movement during an increase in abdominal pressure. The position of the bladder neck is defined with reference to the inferio-posterior margin of the symphysis pubis or to a set of coordinates around the central axis of the symphysis pubis (Schaer GN et al, 1995).

Measurement of bladder neck’s distance from the pubic symphysis are taken at rest and during maximum Valsalva effort and the difference between the two values provides the range of bladder neck movement in millimetres. Early studies showed high reproducibility of such measurements (Schaer GN et al. 1996); although there is no definition of normality regarding bladder neck descent, cut-offs between 15 and 40 mm have been proposed to define urethral hypermobility. Various confounders such as bladder volume, patient’s
position and catheterisation have been shown to influence measurements. An extra challenge in accurately calculating bladder neck descent on ultrasound is standardising an effective Valsalva manoeuvre, especially in nulliparous women who frequently co-activate the levator muscle (Reed H et al. 2004). Transperineal ultrasound imaging of the bladder neck with a standardised Valsalva effort of 40 cmH2O has been used as a method of predicting development of stress urinary incontinence postnatally; bladder neck movement of greater than 1 cm or rotation of urethrovesical angle greater than 40° dictate a 50% chance of persisting postnatal stress urinary incontinence. The risk of postnatal stress incontinence is reduced to 5% if less movement is shown (King JK and Freeman RM 1998).
Figure 3.1.3 Three-dimensional ultrasound image of an asymptomatic nulliparous woman at rest. Pubic bone (PB), urethra (U), vagina (V), puborectalis (PR), uterus and anorectal angle (ARA) are denoted in the sagittal (left) and axial (right) plane.
Another easily visualised feature of the anterior vaginal compartment is the urethrovesical junction where urethral funnelling can be seen in women with stress urinary incontinence, as well as in asymptomatic women (Dietz HP et al. 2002). Funnelling of the internal urethral meatus may be observed on Valsalva and sometimes even at rest and is often, but not always, associated with leakage. Three-dimensional ultrasound scanning can clearly image the urethral sphincter, offering a useful tool to investigate urethral anatomy and function (Robinson D et al. 2004, Toozs-Hobson P et al. 2001). The technique has been validated by correlating urethral images from cadavers with histological findings (Khullar V et al. 1996). With the use of pelvic floor ultrasound researchers have demonstrated that in women with stress urinary incontinence the volume of the urethral sphincter muscle is significantly decreased compared to that of normal controls (Athanasiou S et al. 1999). Evidence has also been provided regarding the predictive value of ultrasound assessment of the urethral sphincter in the outcome following colposuspension, which may be useful in preoperative counselling (Digesu GA et al. 1999).

Pelvic floor ultrasound is a reliable and non-invasive method that can be used for the diagnosis of detrusor overactivity (DO) or DO incontinence through direct measurement of bladder wall hypertrophy, which is associated with DO (Cartwright et al 2011, Oelke M 2010). Increased bladder wall thickness (BWT) - proposed cut-off is 5 mm - has been described in patients with overactive bladder (OAB) or DO and is hypothesised to be associated with detrusor hypertrophy secondary to isometric contractions (Khullar V et al. 1994, Panayi DC et al. 2010). In a recent study of 247 women with DO, SUI, MUI or normal urodynamics, a BWT threshold of 6.5 mm had a 100 % positive predictive value for diagnosing all DO cases (including DO mixed with SUI), and 71.4 % for pure
DO (Serati M et al. 2010). The technique for measuring BWT has been the focus of numerous studies, with the transvaginal approach deemed as the most reliable technique (Panayi DC et al 2010). A recent systematic review has assessed the different techniques employed for BWT measurement and suggested that discrepancies between various described techniques cannot allow for safe conclusions to be drawn regarding their diagnostic accuracy (Latthe PM et al 2010).

Two-dimensional and three-dimensional ultrasound imaging can be used to define the type of anterior vaginal wall prolapse, which can sometimes be difficult to determine by clinical examination only. Two different types of cystocele with different clinical manifestations exist: a cystocele with intact urethrovesical angle, which results in voiding dysfunction and women are less likely to suffer from stress urinary incontinence, and a cystourethrocele which is associated with normal flow rates and urodynamics stress incontinence (Figure 3.1.4) (Schaer GN et al. 1999, Dietz HP et al. 2002)

Three-dimensional ultrasound technique can also be valuable in detecting other pathologies of the anterior vaginal compartment like urethral diverticula, bladder tumours or foreign bodies. Urethral diverticula, which can easily be overlooked in women unless imaging is undertaken, can produce a wide range of urinary symptoms from voiding dysfunction to dysuria and urgency. Vaginal wall thickness (VWT) is another imaging biomarker that has emerged as a result of the advent of pelvic floor ultrasound. Two-dimensional transvaginal ultrasound in measuring VWT has recently been validated and found to correlate well with histological findings of cadaveric vaginal tissue (Panayi DC et al 2010). Assessment of vaginal wall thickness by using a widely available imaging modality may aid clinicians to identify congenital or physiological (menopause) structural causes for primary and recurrent prolapse.
With regard to the posterior vaginal wall compartment, the diagnostic value of pelvic floor ultrasound is restricted. Experienced operators may distinguish between a true rectocele, where the defect lies within the rectovaginal septum, causing prolapse and defaecatory symptoms, and a rectocele that results from an intact but distensible rectovaginal septum, associated mainly with a sensation of a bulge in the vagina (Dietz HP and Korda A 2005). Although the very existence of the rectovaginal septum as an anatomical entity is controversial, pelvic floor ultrasound may provide a cheaper and accessible tool for diagnosing various degrees of posterior vaginal wall defects and hence tailor surgical management accordingly.

Three-dimension ultrasound of the pelvic floor has added much to the identification of the location and type of the increasingly used meshes and slings in urogynaecology. Images reviewed in the axial plane can distinguish between transobturator and retropubic tapes by following the position of the arms (Figure 3.1.5). Moreover, three-dimensional imaging is helpful when assessing women with complications of suburethral slings, such as voiding dysfunction and de novo urgency, helping the surgeon to decide whether loosening or cutting of the sling is required (de Tayrac R et al. 2006). Polypropylene meshes are highly echogenic and thus easily identified in the coronal and axial plane, unless they are obscured by vaginal prolapse. Ultrasound may reveal suboptimal positioning of the implant in the vagina, a feature known as “mesh shrinkage” or “mesh retraction”, a factor which predisposes to prolapse recurrence (Tunn R et al. 2007). Periurethral injectables, used as a continence procedure, can also be depicted with three-dimensional pelvic floor ultrasound. Synthetic implants, like macroplastique, are hyperechogenic, whereas collagen injections are hypoechoic, and can be seen as spherical structures surrounding the bladder neck.
One of the major advantages of the three-dimensional ultrasound imaging of the pelvic floor is the acquisition of static as well as dynamic images of the levator ani muscle and urethral rhabdosphincter muscle. Despite the lower resolution when compared with the endovaginal probes, a three-dimensional translabial curved array probe with a 70–85° acquisition angle produces high quality depiction of the entire levator hiatus including the symphysis pubis, urethra, paravaginal tissues, vagina, anorectum and puborectalis muscle. By analysing the images either on- or off-line, measurements of the urethral sphincter volume, levator hiatal diameters and area, as well as puborectalis and pubovaginalis muscle volumes, can be obtained in order to assess direct and indirect birth-related trauma. There is increasing evidence in the recent literature to support the link between levator ani morphological and functional abnormalities in vaginally parous women with pelvic organ prolapse, and less so in those with stress urinary incontinence (Dietz H and Steensma A 2006, DeLancey JO et al 2003, Kearney R et al 2006).
Figure 3.1.4 Two main types of cystocele as imaged on maximal Valsalva in midsagittal plane: cystourethrocele (green type II\textsuperscript{v}; B), associated with urinary stress incontinence and good voiding function, and isolated cystocele (green type III\textsuperscript{v}; D), associated with prolapse and voiding dysfunction rather than stress incontinence (from Dietz HP. Pelvic floor ultrasound: a review. Am J Obstet Gynecol 2010)

Figure 3.1.5 Three-dimensional ultrasound pelvic floor image of a 56 year-old woman following TVT insertion. The tape is shown as a hyperechogenic structure underneath the mid-urethra in the sagittal(top left), coronal (top right) and axial (bottom) planes. (PB pubic bone, U urethra, PR puborectalis, ARA anorectal angle)

\textsuperscript{*} Radiological classification of cystocele based on bladder neck position, retrovesical angle measurement, and urethral rotation on Valsalva by Green (Green TH Jr. 1975) and modified by Blaivas and Olsson (Blaivas JG and Olsson CA 1988).
The concept of levator ani trauma (detachment) was proposed and extensively studied by Dietz and colleagues (Dietz HP and Lanzarone V 2005). The authors suggested that major delivery-related levator trauma (avulsion injury), affecting the inferomedial aspects of the puborectalis muscle, comprise the missing link between vaginal childbirth and prolapse (Figure 3.1.6). It has been proposed that levator avulsion enlarges the hiatus and results in anterior and central compartment prolapse, with the likelihood of prolapse increasing as the defect gets greater (Dietz H, Simpson J 2008). Women with such defects were found to be twice as likely to show pelvic organ prolapse of stage II or higher than those without, suggesting a far more prominent role of avulsion injury in prolapse than factors previously proposed, such as direct and indirect trauma, altered biomechanics of pelvic floor or fascial defects.

3.1.3 Pelvic floor MRI

The advent of high resolution MRI techniques has offered considerable insight into the aetiology of the pelvic floor structural defects. Magnetic resonance imaging is deemed superior to fluoroscopy, which was considered the gold standard for more than 20 years in detecting pelvic floor abnormalities. Without using ionising radiation, MRI’s high soft tissue and temporal resolution can capture ligamentous and muscular pelvic floor structures in fine detail; however, the considerable cost of the technique and the need for specialist radiological interpretation are the main disadvantages for its use. In static MRI of the pelvic floor, no previous patient preparation is required. The modality relies on static sequences with a high spatial resolution to delineate the passive and active elements of the pelvic organ support system. Most commonly, images are acquired in axial, sagittal and coronal planes. The patient is placed in the supine position, unless an open magnet is available,
wherein the images can be obtained with the patient seated. The MRI protocol would usually involve T2-weighted turbo spin-echo (TSE) sequences with slice thickness of 5 mm and gap of 0.7 mm.

Several studies have shown that MRI is a useful method for diagnosing and staging pelvic organ prolapse, with detection rates similar to fluoroscopic techniques, and that MRI is often able to reveal more extensive organ prolapse than physical examination alone (Hetzer FH et al. 2006, Kelvin FM et al. 2000). In order to determine the presence and extent of prolapse with MRI, several lines and levels of reference have been proposed. The most commonly used ones are either a line drawn from the inferior margin of the pubis symphysis to the last coccygeal joint (pubococcygeal line—PCL) or a line extending caudally along the longitudinal axis of the symphysis pubis in the sagittal plane, noted as midpubic line (MPL) (Figure 3.1.7). The choice of reference line is dependent on the radiologist performing the imaging and the referring clinician, as neither has been shown to have better agreement with the clinical staging of the prolapse than the others (Singh K et al. 2001, Etlik Ö et al. 2005, Woodfield CA et al. 2009). Notably, the MPL seems to correspond to the level of the hymen as shown by studies on cadaveric dissection (Singh K et al. 2001). The largest measurement from the leading point of the organ in study (bladder base, cervix/vault or anorectal junction) perpendicular to the reference line during straining or evacuation is used to stage the presence and degree of pelvic organ prolapse; prolapse severity can be graded according to the “rule of three”: prolapse of an organ below the PCL by 3 cm or less is mild, between 3 and 6 cm is moderate, and more than 6 cm is severe (Tables 3.1 and 3.2) (Lienemann A et al. 1997, Goh V et al. 2000). The MRI-based HMO classification system provides a straightforward and reproducible method for
quantifying pelvic floor relaxation and organ prolapse (Comiter CV et al. 1999) (Figure 3.1.7).

The puborectalis muscle is seen as a separate structure on MRI lateral to the pubovisceralis. The pubovisceralis and puborectalis are best imaged in the axial and sagittal planes, whereas the iliococcygeus muscle is better visualised in the coronal plane. There is considerable variation in the levator ani size and thickness between individuals, which needs to be taken into account during interpretation of MRI findings (DeLancey JO et al. 2003, Tunn R et al. 2003). The impact of vaginal delivery on the various components of the levator ani muscle has been well studied with the use of MRI of the pelvic floor. It has been shown that during vaginal birth the strain forces to the pelvic floor can cause the levator ani to stretch as much as 320% of its original length (DeLancey JO et al 2003). Up to 20% of parous women may sustain injury to the levator ani, and this risk is associated with forceps delivery, anal sphincter tears and episiotomy (Kearney R et al. 2006). More than 50% of women with significant pelvic organ prolapse were found to have major defects of the levator ani muscle in a case-control study with the use of pelvic floor MRI. The proportion of cases with major defects was significantly higher than that of age-, race-, and hysterectomy-matched controls (Figure 3.1.8) (DeLancey JO et al. 2007).
Figure 3.1.6 Unilateral avulsion of the puborectalis muscle in rendered volume of axial plane; long arrow showing right arm of puborectalis muscle and short arrow showing retracted right arm of puborectalis muscle due to a defect (P, puborectalis muscle; R, rectum; S, symphysis pubis; V, vagina - from Dietz HP 2010)
Table 3.1. MRI staging of POP with MPL as reference

<table>
<thead>
<tr>
<th>Stage</th>
<th>criteria&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>&gt; 3 cm to (TVL&lt;sup&gt;b&lt;/sup&gt; – 2 cm) above MPL</td>
</tr>
<tr>
<td>1</td>
<td>Does not meet stage 0, but &gt; 1 cm above MPL</td>
</tr>
<tr>
<td>2</td>
<td>≤ 1 cm above or below MPL</td>
</tr>
<tr>
<td>3</td>
<td>&gt; 1 cm below MPL</td>
</tr>
<tr>
<td>4</td>
<td>Complete organ eversion</td>
</tr>
</tbody>
</table>

<sup>a</sup> Distance of inferior bladder base, anterior cervical lip, and anterior anorectal junction from MPL.

<sup>b</sup> On physical examination and sagittal MR images, total vaginal length (TVL) is the greatest vertical vaginal measurement in centimetres from the posterior vaginal fornix to the level of the introitus in patients with a cervix. In patients without a cervix, the measurement is made from the most superior aspect of the vaginal cuff to the level of the introitus.

Table 3.2. MRI staging of POP with PCL as reference

<table>
<thead>
<tr>
<th>Stage of prolapse</th>
<th>criteria&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>1 to &lt; 3 cm below PCL</td>
</tr>
<tr>
<td>Moderate</td>
<td>3–6 cm below PCL</td>
</tr>
<tr>
<td>Large</td>
<td>&gt; 6 cm below PCL</td>
</tr>
</tbody>
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<sup>a</sup> Distance of inferior bladder base, anterior cervical lip, and anterior anorectal junction from PCL.
Figure 3.1.7 Sagittal MRI image of the pelvic floor obtained at rest in a 50-year-old normal volunteer woman. The H line is drawn from the inferior border of the pubic symphysis to the posterior wall of the rectum at the level of the anorectal junction. The M line is drawn perpendicularly from the PCL to the most posterior aspect of the H line. The H and M lines, along with O (for organ prolapse) constitute the reference lines for HMO classification (Comiter CV et al. 1999)

(PCL: pubococcygeal line, black arrow: bladder base, white arrow: vaginal vault, *: anorectal junction, from Colaiacomo MC et al. 2009)

Figure 3.1.8 Examples of grades of unilateral defects in the pubovisceral portion of the levator ani muscle in axial magnetic resonance images at the level of the mid urethra. The score for each side is indicated on the figure, and the black arrows indicate the location of the missing muscle (A. grade 1 defect; B. grade 2 defect; and C. grade 3 defect , from DeLancey. Levator Ani Impairment in Prolapse. Obstet Gynecol 2007)
The anal sphincter complex can be visualised in both the axial and coronal planes. The internal anal sphincter muscle (IAS) is the innermost muscle and is uniformly intermediate in signal intensity on T2-weighted images. The external anal sphincter muscle (EAS) is the outermost muscle and is usually lower in signal intensity on T2-weighted images. The EAS may be open anteriorly or posteriorly as a normal variation and this should not been regarded as a defect (Hodroff MA et al. 2002). Pelvic floor MRI is equally accurate (91%) to endoanal ultrasound in detecting anal sphincter defects and more accurate (93%) than ultrasound in demonstrating sphincter atrophy (Rociu E et al. 1999).

Static MRI imaging of the pelvic floor has been used to study the mechanism of urinary incontinence. In continent women the levator plate lies more parallel to the pubococcygeal line (PCL) and the bladder neck is higher above the PCL and closer to the symphysis pubis, when compared with women with urodynamic stress incontinence (Goodrich MA et al. 1993 and Yang A et al. 1991). Pelvic floor MRI has also helped assess the way some continence procedures work; a shorter distance between the levator ani muscle and the bladder neck was noted in the sagittal and parasagittal MRI pelvic floor images of women who underwent successful Burch colposuspension (Digesu GA et al. 2004).

Visualisation of the endopelvic fascia and the ligamentous structures providing support to the viscera still remains challenging with the current MRI modalities. Relatively recent data, however, have provided an insight in the supportive structures of the urethra and the vagina (Macura KJ et al. 2006). The authors successfully depicted and described three different ligaments that provide support to the female urethra: the periurethral, paraurethral and pubourethral ligaments, which had previously been a point of controversy in anatomy textbooks and imaging studies.
3.1.4 Endoanal MRI

Endoanal MRI, with the use of an endocoil, is admittedly a more complex and time-consuming modality than endoanal ultrasound; however it provides higher quality images of the anal sphincter muscle complex. The examination is carried out with the use of a lubricated sheathed coil which is inserted into the anus with the woman in the left-lateral position. Subsequently, the woman is turned onto the supine position and images are taken in the axial plane. The bladder is emptied prior to the investigation, which normally does not last for more than 30 min. Alternatively, if the placement of the endocoil in the rectum is not tolerated, an externally placed phased array coil can be employed to facilitate sphincter depiction, however the quality of the images is operator dependent.

The main indication for endoanal MRI with regard to pelvic floor dysfunction is assessment of anal sphincter volume. MRI is superior to endoanal ultrasound in measuring the EAS thickness which is normally around 4 mm (Rociu E et al. 1999). External anal sphincter atrophy is defined by thinning of the muscle and replacement by fat; less than 50% thinning of the muscle is considered as moderate atrophy, whereas >50% thinning and muscle fibre replacement by fat is deemed as severe atrophy (Williams AB et al. 2001 and Terra MP et al. 2006).

Endocoil MRI seems to be equally effective as endoanal ultrasound in depicting anal sphincter tears. Similar positive predictive values between the two modalities in detecting patients with anal sphincter tears, that subsequently required surgical repair, have been reported (Dobben AC et al 2007). Overall, endoanal ultrasound remains the investigation of choice for diagnosing
suspected anal sphincter injury as it is quicker, less costly and by and large more readily available.

3.2 Dynamic imaging

3.2.1 Fluoroscopy

For more than 20 years, fluoroscopy of the pelvic floor has been the gold standard in detecting vaginal prolapse in women with urinary and defaecatory symptoms. Despite the advent of new dynamic imaging modalities such as dynamic MRI and four-dimensional ultrasound, fluoroscopic techniques such as voiding cystourethrography (VCUG), evacuation proctography, cystoproctography and cystocolpoproctography are still of great value mainly due to their wide availability, low cost and their ability to depict on pelvic floor abnormalities with the patient in a physiological position, either standing or seating. On the other hand, disadvantages of the technique include the more invasive nature of the investigation, the use of ionising radiation, the need for contrast and the inability to simultaneously evaluate all three pelvic compartments.

Voiding cystourethrography (VCUG) is used in women with complex history of lower urinary tract symptoms and anterior compartment prolapse. Indications include neurogenic bladder, previous anterior vaginal wall prolapse or/and continence surgery and refractory idiopathic detrusor overactivity. The patient is imaged in the lateral standing position after the bladder has been filled with iodinated contrast. Images are taken during rest, coughing and voiding to assess for any bladder base descent. Evaluation and diagnosis of vesicourethral reflux, bladder and urethral diverticula and bladder wall trabeculations are also
among the scopes of this imaging technique (Figure 3.2.1) (Pelsang RE and Boney WW 1996).

With regards to the posterior compartment, evacuation proctography (or defecating proctography) is the fluoroscopic technique used for assessing rectal evacuation and posterior vaginal wall prolapse in women with constipation and defecatory dysfunction. The study is based on voluntary evacuation of paste enema (barium) administered into the rectum through a syringe. If an enterocoele is suspected, oral medium contrast can be administered 2 h prior to the study to assess the small bowel. The patient is then seated on a commode placed on the footrest of the X-ray table, and continuous imaging by videofluoroscopy is performed before, during and after evacuation. Five criteria need to be met for a defecating proctogram to be considered normal as shown in a series of asymptomatic volunteers: increased anorectal angulation, obliteration of the puborectal muscle impression, wide anal canal opening, total evacuation of contrast and normal pelvic floor resistance (Mahieu P et al. 1984, Shorvon PJ et al. 1989).

Pelvic floor descent can be measured with reference to fixed bony landmarks in the sagittal plane. The most commonly used reference points are the PCL and MPL, as described previously for the pelvic floor MRI. The PCL is the line that corresponds to the pelvic floor (Bartram C et al 2001). The anorectal angle (ARA), the angle between the anal canal axis and the posterior upper rectum, reflects the status of the puborectalis muscle, which forms a sling around the posterior aspect of the anorectal junction.
Figure 3.2.1 VCUG image of a 46-year-old female presenting with neurogenic detrusor overactivity. The bladder has trabeculation and bladder diverticulae with a wide open bladder neck.
In general, ARA is normally approximately 90° at rest; however, the clinical value of this measurement is questionable (Taylor SA 2009). In the absence of anatomical or functional pathology, complete evacuation involves pelvic floor descent, relaxation of the puborectalis and anal sphincter muscles with decreased impression of the puborectalis on the posterior rectal wall (wider anorectal angle). Following evacuation, the reverse sequence of events takes place and so the anatomic structures return to their pre-evacuation position. Apart from assessing rectal evacuation, proctography can also depict rectal prolapse, rectocoele and rectal intussusception which also result in dysfunctional defaecation. Rectal intussusception can be shown as invagination of the rectum on itself or into the anal canal. Rectocoele is defined as a protrusion of the anterior wall of the rectum wall more than 2 cm from a line drawn along the axis of the anal canal. Another cause of constipation which can be elucidated by evacuation proctography is absent or delayed rectal emptying due to the inability of the puborectalis muscle to relax during voluntary evacuation. The condition is known as “pelvic dyssynergy” or “paradoxical puborectalis contraction” or “anismus”, and can be diagnosed if more than 66% of rectal contrast material is not evacuated within 30 seconds (Halligan S et al. 2001).

When multi-compartmental imaging is required, dynamic cystocolpoproctography is the fluoroscopic technique of choice. The technique involves opacification of the rectum, bladder, vagina and small bowel to facilitate functional imaging of organs in all pelvic compartments at the same time. Despite the simplicity of an approach involving concurrent opacification of the pelvic organs, the argument against the validity of this technique is based on the presumption that prolapsed organs are competing for space in the pelvis and thus may obscure the true severity of prolapse in any given
compartment (Kelvin FM et al 1992). Instead, a staged approach, which allows for assessment of the different compartments separately without the risk of masking a prolapsed organ, has been suggested as a preferable technique (Kelvin FM et al. 2000).

3.2.2 Dynamic pelvic floor MRI

Aside its potential as static imaging modality, dynamic MRI is a valuable complementary tool in the assessment of the urogynaecological patient with multi-compartmental defects. Depending on the protocol recruited, MRI can effectively study defecatory dynamics either via an open or closed magnet, without the use of contrast medium (Bertschinger KM et al. 2002). Some protocols involve the administration of ultrasound gel or other media to opacify the rectum and facilitate imaging during defecation, especially when intussusception is suspected. Dynamic MRI is performed in the midsagittal plane with the slice adjusted so that all the pelvic organs are visualised. Using a rapid image sequence, such as fast imaging with steady state precession or single shot fast spin echo, images are obtained every second as the patient performs various manoeuvres (Kegel, maximum Valsalva, voluntary defecation). Rectal intussusceptions can be diagnosed by the presence of rectal wall in-folding from the mid-rectum towards the anal canal. Intussusception is considered low grade if the in-folding wall is thin and is confined to the rectum. In high-grade intussusception, the in-folding is thicker and may enter lower in the upper anal canal (Oxford scale). The sensitivity of MRI in diagnosing rectal intussusceptions, however, has been reported to be lower than that of evacuation proctography (Comiter CV et al. 1999). Pelvic floor descent is often seen on dynamic MRI during Valsalva manoeuvre. Such finding needs to be regarded with reference to the patients’ history and clinical
symptoms. For example, pelvic floor descent can be attributed to pudendal neuropathy, if the patient is complaining about defecatory dysfunction which leads to prolonged and excessive straining. On the other hand, prolapse symptoms and incontinence are more likely to be linked to pelvic floor muscle and fascial defects due to trauma during childbirth, resulting in pelvic floor descent through structural defects. Due to its very high soft tissue resolution, dynamic MRI can reveal complex pelvic floor weaknesses that are difficult, if possible, to be diagnosed clinically (Figure 3.2.2). Sigmoidocoeles, enterocoeles and peritoneocoeles can be imaged without the use of contrast in the sagittal plane adding significant information about the patient’s symptomatology and offering guidance in choosing the best surgical approach.

3.2.3 Three- and four-dimensional pelvic floor ultrasound

Three- and four-dimensional ultrasound imaging of the pelvic floor has enhanced the clinical approach to complex urogynaecology conditions. It is increasingly available in tertiary urogynaecology centres. As mentioned previously in static imaging, 3D ultrasound allows unlimited multi-planar images to be obtained, which is of high value when limited access to the bony pelvis is available. Four-dimensional transperineal / translabial ultrasound offers the ability to record the dynamic functional anatomy of the pelvic floor without the restrictions of transferring the patient to a radiology suite for a fluoroscopic investigation or MRI, or the use of ionising radiation and contrast medium. The technique does not require input by a radiology specialist as it can be performed by the clinician to supplement their clinical examination and facilitate diagnosis. Depending on quality settings and acquisition angles, modern ultrasound scanners are capable of obtaining 0.5–20 volumes per second producing cine loops of volume data that can depict morphological
changes of the pelvic floor structures during provocative manoeuvres (contraction, Valsalva). The ability to acquire real-time volume data sets of the pelvic floor anatomy with ease makes 4D transperineal ultrasound superior to MRI (Taylor SA 2009). Prolapse assessment by magnetic resonance requires ultrafast acquisition, which is not widely available and does not allow for optimal resolutions (Yang A et al 1991). Moreover, real-time 4D ultrasound imaging allows identification and controlling for confounders, such as suboptimal performance of provoke manoeuvres, often seen during Kegel contraction or co-activation of levator ani muscles during Valsalva, which cannot be depicted on MRI (Oerno A and Dietz H 2007).
Figure 3.2.2 Severe uterine prolapse in a 41-year-old woman. Sagittal function MRI image obtained during defecation shows the uterus moving downward inside the vagina and the cervix exits the vaginal introitus (white arrow). H and M lines are abnormally elongated. Urethral funnelling without hypermobility (arrowhead) and severe posterior compartment descent (black arrow) are also noted (from Colaiacomo et al. 2009)
3.3 Discussion and research hypotheses

Increasing awareness of the prevalence and complexity of pelvic floor dysfunction necessitates a combined approach by incorporating clinical examination to new imaging modalities to establish diagnosis and optimise treatment. The advent of three-dimensional / four-dimensional ultrasound imaging of the pelvic floor functional anatomy has opened new horizons in the assessment of the patient in the urogynaecology clinic, without the need for complex and interventional imaging techniques. Even though urodynamic investigations remain the gold standard for the investigation of lower urinary tract symptoms and clinical examination comprises the main route for assessing pelvic organ prolapse, the advent of non-invasive imaging modalities has offered urogynaecologists and allied healthcare professionals an additional tool in both the clinical and research setting. Before such new imaging modalities are well established in clinical practice though, well-designed and sufficiently powered studies will have to prove their ability in linking clinical manifestations with image findings. This is underlined in the most recent IUGA-ICS joint report on the terminology for female pelvic floor dysfunction: “The potential of 3D ultrasound in urogynecology and female urology is currently being researched with validated applications likely to be included in future updates of this report and/or separate ultrasound reports. Applications with the most current research include: (i) major morphological abnormalities such as levator defects and (ii) excessive distensibility of the puborectalis muscle and levator hiatus (“ballooning”). The additional diagnostic potential of 4D (i.e., the addition of movement) ultrasound awaits clarification by further research” (Haylen BT et al. 2010).
From the preceding literature the following hypotheses are formed:

**Null hypothesis 1**
The pelvic floor is an anatomical complex consisting of musculature (pelvic diaphragm muscles and urogenital diaphragm muscles), ligaments and connective tissue, which are interconnected in a three-dimensional arrangement. The interaction between the vagina and its supportive structures, as well as their behaviour under the mechanical load of increased abdominal pressure can be modelled as a biomechanical system (Abramowitch SD et al 2009), but studies in humans are very rare. It is hypothesised that:

**The biomechanics of the female pelvic floor cannot be studied in real time with the use of 3D/4D translabial ultrasound.**

**Null hypothesis 2**
Urinary incontinence (UI) is a highly prevalent symptom that affects millions of people worldwide of both sexes and all ages. Urodynamic stress incontinence represents the commonest cause of incontinence in women, affecting up to 60% of those investigated (Andrada Hamer M et al 2011). The urethral sphincter is believed to play an important role in the pathogenesis of lower urinary tract symptoms, hence information on its structure and function is vital to develop our understanding of urinary incontinence (Wang HJ et al. 2011).

Although the clinical value of accurately and precisely evaluating the urethral sphincter using a 3D ultrasound is evident, its reliability has been poorly studied to date. It is hypothesised that:

**Translabial three-dimensional ultrasound imaging is a not a reliable and accurate technique for assessing female urethral sphincter.**
Null hypothesis 3
The lower urinary tract symptoms and underlying pathology varies in prevalence depending on the population studied and definitions used. Recent studies have examined the difference in prevalence, frequency and severity of urinary incontinence types between different races (Thom DH et al. 2006). It is hypothesised that:

The different prevalence of SUI between black and white women cannot be attributed to differences in the urethral sphincter or levator ani hiatus morphology depicted in 3D/4D translabial ultrasound of the pelvic floor.

Null hypothesis 4
Although vaginal delivery has been well established as a significant risk for the subsequent development of pelvic floor dysfunction in the long-term (Mant J et al. 1997, Viktrup L et al. 1992), the type and incidence of pelvic floor injury caused during vaginal birth that results in pelvic floor disorders are still controversial. Levator ani muscle (LAM) defects have been reported in women both symptomatic and asymptomatic for prolapse. In a case-control study with the use of MRI, major injuries of the LAM were found in 55% of women with POP and in 15.6% of controls (DeLancey JO et al 2007). Furthermore, in a similar case-control study with the use of 3D/4D pelvic floor ultrasound, 23% of women with significant prolapse (POP-Q stage II or higher) demonstrated either unilateral or bilateral avulsed puborectalis muscle, whereas the presence of such defects was noted in 11% of women without prolapse (Dietz H and Simpson J 2008). Case–control studies do not allow an estimation of the prevalence of LAM trauma among all women and depiction of LAM injuries varies significantly among different imaging modalities. It is hypothesised that:

The prevalence of pubovisceral muscle (PM) avulsion in a general gynaecological cohort of women estimated with the use of spiral CT of the
pelvic floor is similar to that previously reported in urogynaecological cohorts via different imaging modalities.

**Null hypothesis 5**

Three- and four-dimensional ultrasound imaging has been shown to have good intra- and inter-observer reliability in the assessment of the levator hiatus (LH) dimensions (Braekken IH et al. 2008). On the other hand, the size of the urogenital hiatus (GH), measured during vaginal examination using the POP quantification system, has been shown to correlate with the severity of POP and prolapse recurrence after surgery (Delancey JO and Hurd WW 1998). It is hypothesised that:

Three- and four-dimensional ultrasound imaging of the pelvic floor is not of additive value to the clinical assessment of women with POP and is not useful in evaluating the outcome of surgical repair of vaginal prolapse.
CHAPTER 4

Real time in vivo ultrasound study of pelvic floor biomechanics
Chapter 4: Real time in vivo ultrasound study of pelvic floor biomechanics

4.1 Summary

Objective: To study the deformation of the levator ani muscle in vivo with the use of real-time ultrasound imaging of the pelvic floor.

Study design: Thirty-two women with symptoms of pelvic floor dysfunction underwent real-time in vivo assessment of the strain of the pelvic floor during Valsalva effort. All participants underwent clinical examination, urodynamics and 3D/4D translabial ultrasound scan of the pelvic floor. The deformation curves of the levator ani muscle were plotted and the difference in compliance according to the grade of urogenital prolapse was measured. One-way ANOVA and Spearman’s correlation were used to test for significance of the relationship between variables (significance level $P < 0.05$). Test–retest analysis of the ultrasound measurements of the levator hiatal dimensions was also conducted using intra-class correlation coefficient (ICC).

Results: The deformation curve of the levator hiatus showed a non-linear relationship with gradually increased Valsalva force, which was quite pronounced in the pubourethralis subdivision of the levator ani muscle complex. Women with significant pelvic organ prolapse demonstrated a less compliant levator ani muscle close to its origin from the pubic bone than women with non-significant prolapse (median maximum strain 26% vs 32%, respectively, $P = 0.03$).

Conclusions: Real-time in vivo assessment of pelvic floor biomechanics in women is feasible and yields significant information.
4.2 Introduction

Pelvic floor disorders comprise a wide spectrum of interrelated clinical conditions including pelvic organ prolapse (POP), urinary incontinence (UI), faecal incontinence (FI) and voiding dysfunction. It has been calculated that almost one third of premenopausal women and half of postmenopausal women suffer from symptoms of pelvic floor dysfunction and that a woman’s lifetime risk of undergoing surgery for POP or a related condition is 11% (Olsen AL et al 1997).

Support to the pelvic viscera is provided directly by the vagina and indirectly by the anatomical structures involved in the vaginal support. The pelvic floor is an anatomical complex consisting of musculature (pelvic diaphragm muscles and urogenital diaphragm muscles), ligaments and connective tissue, which are interconnected in a three-dimensional arrangement (Ashton-Miller JA and DeLancey JO 2007). The interaction between the vagina and its supportive structures, as well as their behaviour under the mechanical load of increased abdominal pressure can be modelled as a biomechanical system (Abramowitch SD et al. 2009). Biomechanics is the application of mechanics (i.e. measurement of force, motion, stress, strain, deformation, etc.) to biological systems. Most biological specimens demonstrate a mixture of elastic, viscous and plastic properties; the elasticity and viscosity of a biological tissue are responsible for allowing its deformation whenever a load is exerted upon it, whereas the plasticity of the tissue is responsible for any residual deformation over time (Goh JT 2003).

Despite the demonstration of such biomechanical properties in animal studies (Abramowitch SD et al. 2009), there is scarce evidence of the behaviour of human vaginal tissues under abdominal load (stress). Age-related differences
in the elasticity of the anterior vaginal wall tissues have been demonstrated in women, showing a less elastic vaginal tissue in the postmenopausal group (Goh JTW 2002). Boreham and co-authors showed that women with POP had a smaller fraction of smooth muscle in their vaginal tissue as a result of injury or denervation, irrespective of age and hormonal status, when compared to women without prolapse (Boreham MK et al 2002).

The physiological mechanism by which pelvic floor muscles and endopelvic fascia resist deformation of the tissues when abdominal pressure is exerted can be better understood with in vivo real-time investigations. Palpation, inspection, electromyography, ultrasound, and magnetic resonance imaging (MRI) are different methods of evaluating pelvic floor muscle (PFM) function. Although vaginal palpation can serve as an initial assessment of the pelvic floor muscle activity, ultrasound and MRI seem to offer more objective assessment of the function of this complex unit (Bø K and Sherburn M 2005). The vast majority of such studies have used computerised 3D models derived from static and dynamic images. In the only in vivo real time ultrasound study available to date, imaging of the levator hiatal strain was proven reliable and the strain at contraction seemed to correlate well with muscle strength as assessed clinically (Thyer et al. 2008).

In the present study we measure the changes in dimension of the levator ani muscle (LAM) during Valsalva manoeuvre, in vivo, with real time translabial 3D/4D ultrasound in women with pelvic floor dysfunction (PFD). The deformation curve of the LAM during Valsalva effort is also explored by using indirect measurement of the intra-abdominal pressure.
4.3 Methods

In this observational study, women with symptoms of pelvic organ prolapse (POP) and lower urinary tract symptoms (LUTS) were recruited at a tertiary referral urogynaecological centre. Women presenting in the urodynamics and video-urodynamics clinic were approached to participate in the study and the full protocol was explained in detail. Previous surgery for POP or/and stress urinary incontinence (SUI) was an exclusion criterion for the present study. All participants signed a consent form based on the granting of ethical approval by the local ethics committee (NRES Committee London-Surrey Borders, Ref No.: 10/H0806/21).

All participants underwent a clinical interview and prolapse assessment using the prolapse quantification system (POPQ) according to the standards proposed by the International Continence Society (ICS). Filling and voiding cystometry or videocystourethrography (VCU) was performed according to the principles described in the International Urogynecological Association (IUGA)/ICS Joint Report on the Terminology for Female Pelvic Floor Dysfunction (Haylen BTet al 2010). At the end of the pressure-flow study, translabial 3D/4D ultrasound scan of the pelvic floor was performed, with the rectal fluid-filled catheter in situ to allow indirect measurement of gradually increased abdominal pressure. The ultrasound scan was performed with a 4–8 MHz curved array probe (Voluson i, GE, Wauwatosa, WI, USA) placed translabially with the woman in the semirecumbent position. All scans were performed by the same experienced urogynaecologist in pelvic floor scanning (AD).

Women were asked to blow four times with increasing force on a Valsalva leak point pressure (VLPP) mouthpiece (Laborie Medical Technologies, Canada) and
hold for 3–5 s to standardise the Valsalva manoeuvre. A test run was conducted by each patient prior to the main recording to allow for best consistency with Valsalva effort. The abdominal pressures (Pabd) generated with each effort were recorded on the urodynamic machine and women were asked to watch the graph on the monitor in real time, while instructed to achieve a target pressure. Ultrasound images of the pelvic floor were taken at rest and at Pabd of 10, 20, 30 cm and at the pressure level generated with maximum Valsalva effort. Since all participants were able to generate a maximum pressure of 50 cm H2O, increments of 10, 20, 30, 40 and 50 cm H2O were used for analysis.

Measurements of the LH anterior–posterior diameter, transverse diameter at two different anatomical subdivisions of the pubovisceralis muscle (pubourethralis and pubovaginalis muscles), and area were taken in the axial plane both at rest and at the aforementioned pressure points during the Valsalva manoeuvre. The reference plane for measurements was that of the minimal hiatal dimensions (Figure 4.3.1), as previously described (Dietz H 2007). Deformation of the levator hiatus is represented by change in the dimensions of the pubovisceralis muscle (PV), which is the most medial part of the vertical portion of the LAM complex in the axial plane (Figure 4.3.1). More precisely, the pubovaginalis muscle comprises the attachment of the PV muscle to the vaginal wall, whereas the pubourethralis muscle forms its attachment to the endopelvic fascia passing underneath the urethra. These muscles are in essence part of the same muscle (pubovisceralis) and along with the puborectalis muscle allow the viscera to be pulled anteriorly and cephalad towards the pubic bone, thus closing the levator hiatus.
Figure 4.3.1 3D ultrasound image of the pelvic floor at rest showing the anatomy and the reference plane of measurements. Left: sagittal view; PB: pubic bone; U: urethra; V: vagina; ARA: anorectal angle; white line: plane of minimal hiatal dimensions (plane of all measurements). Right: axial view; PB: pubic bone; U: urethra; V: vagina; R: rectum; PV: pubovisceralis muscle; black line: antero-posterior diameter of the levator hiatus; white line: transverse diameter of the levator hiatus at the level of pubourethralis, white double-arrowed line: transverse diameter of the levator hiatus at the level of pubovaginalis.
The deformation (e) of the levator hiatus area, anterior–posterior diameter and transverse diameter at the level of the pubourethralis and pubovaginalis portions was calculated with the formula derived by Hooke’s law, \( e = \frac{Dh}{ho} \) (\( Dh \) is the difference between measurements of the biometric index at each pressure point during Valsalva and at rest, \( ho \) is the measurement of the biometric index at rest). We used Hooke’s law to calculate the deformation curve of the levator hiatus due to the fact that, although a non-linear response of biopsied vaginal tissues in large deformations has been shown (Jean-Charles C et al. 2010, Rubod C et al. 2008), good approximation in measuring the strain of biological tissue can be achieved with the use of a linear formula, when small loads (here abdominal pressures) are considered (Treloar LRG 1975).

The deformation curves of the LH with gradually increased abdominal pressure were obtained to characterise the behaviour of the pelvic floor. One-way ANOVA and Spearman’s correlation were used to test for significance of the relationship between variables (significance level \( P < 0.05 \)). Prior to analysing the parameters of the LH deformation, a test–retest analysis of the ultrasound measurements was conducted in 10 randomly chosen sets of images by the same assessor (AD), using the intraclass correlation coefficient (ICC). Power calculation was not deemed necessary, as this constitutes a pilot study.

4.4 Results

Thirty-two women with symptoms of pelvic floor dysfunction were studied in total. Three participants were excluded from further analysis due to their inability to perform the Valsalva manoeuvre effectively as instructed. The mean age of the participants was 53 years (range 23–78) and the mean BMI was 26.5 ± 1.25 (SD) kg/m². The clinical characteristics of the 29 women included in the final analysis are shown in Table 4.1.
Levator hiatal antero-posterior measurements at rest and Valsalva at different pressure points showed excellent repeatability (ICC = 0.95 and 0.88–0.92, respectively). Intraclass correlation coefficient values were also high for LH measurements in the transverse diameter at the same pressure levels (0.92 and 0.87–0.90 at the level of pubovaginalis, 0.89 and 0.88–0.90 at the level of pubourethralis, at rest and at Valsalva respectively). The deformation curves for the LH antero-posterior and transverse diameters at the level of the pubovaginalis subdivision showed a mildly non-linear relationship with gradually increased Valsalva force, especially beyond the pressure level of 40 cm H2O (Fig. 4.3.2). The deformation of the LH in the transverse diameter at the most cephalad section of the pubovisceralis muscle demonstrated a highly non-linear stress–strain curve, implying a less compliant pelvic floor closer to the origin of the LAM from the pubic bone (Fig. 4.3.3).

With regard to the differences in deformation of the LH between different stages of prolapse, women with significant prolapse (POP stage ≥ 2) demonstrated a lower strain, in other words a less compliant LH at the level of the pubourethralis subdivision, than women with mild or no prolapse (P = 0.03). The same trend was evident for the antero-posterior and transverse diameter at the level of the pubovaginalis portion, but statistical significance was not reached (P = 0.76). Figure 4.3.4 shows the graphic representation of the relationship between the degree of prolapse and the maximum deformation of the LH in the two subdivisions of the PV muscle.
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Table 4.1 Characteristics of participants
Figure 4.3.2. Deformation curve of the levator hiatus in the transverse diameter at the level of the pubovaginalis subdivision of the pubovisceralis muscle and corresponding 3D ultrasound image of the levator hiatus. The x-axis of the graph denotes pressure in cm H2O and the y-axis strain as % (PB: pubic bone; U: urethra; V: vagina; R: rectum; PV: pubovisceralis muscle; LHt-v: transverse diameter of the levator hiatus at the level of pubovaginalis muscle).

Figure 4.3.3 Deformation curve of the levator hiatus in the transverse diameter at its most cephalad part, close to its origin from the pubic bone and corresponding 3D ultrasound image of the levator hiatus. The x-axis of the graph denotes pressure in cm H2O and the y-axis strain as % (PB: pubic bone; U: urethra; V: vagina; R: rectum; PV: pubovisceralis muscle; LHt-u: transverse diameter of the levator hiatus at the level of pubourethralis muscle).
Figure 4.3.4 Box plot graph denoting the maximum strain of the levator hiatus (as %) in the transverse diameter at the two distinct subdivisions of the pubovisceralis muscle according to different stage of prolapse [left: level of pubovaginalis muscle (PVM); right: level of pubourethralis muscle (PUM)].
4.5 Discussion

The current study demonstrates the excellent repeatability of the ultrasound measurement of the LH dimensions, proving that real-time in vivo study of the deformation of the pelvic floor with 3D/4D translabial ultrasound is feasible and reliable. The study explores the changes in dimensions of the LAM in women with PFD in vivo, under progressively increased abdominal pressure with the use of translabial ultrasound imaging. The deformation of the LH is characterised by a non-linear response to application of gradually increased force on the pelvic floor during Valsalva manoeuvre. This deformation, conveyed to the pubovisceralis portion of the levator ani, is uneven at its different anatomical subdivisions; the strain of the pubovisceralis at its most cephalad part, close to its origin from the pubic rami bilaterally, is pronouncedly non-linear, implying a less compliant tissue with prominent viscoelastic properties. The sub-analysis of these tissue properties according to the degree of prolapse revealed that in women with significant prolapse the pelvic floor was less compliant than in women with mild or no prolapse, and more so in the anterior than in the central vaginal compartment.

Our results corroborate the findings of previous mechanical studies in human prolapsed and non-prolapsed tissues. In a case-control study by Lei and co-authors it was concluded that while both prolapsed and non-prolapsed tissues possess non-linear viscoelastic properties, the anterior vaginal wall of women with POP showed reduced elasticity (lower compliance) compared to that of healthy controls (Lei L et al. 2007). The non-linear response of prolapsed and non-prolapsed vaginal tissues was confirmed in yet another study by Rubod et al.; the authors noticed a more pronounced non-linear strain response of prolapsed vaginal tissue to stress in comparison to that of normal vaginal tissue (Rubod C et al. 2008). Additional confirmation came recently from a
study comparing samples from both the anterior and the posterior vaginal walls obtained from women with prolapse to fresh cadaveric samples, which served as controls. Jean-Charles and co-authors concluded that prolapsed tissues in both vaginal compartments were more rigid than the non-prolapsed ones and proved that the rigidity was higher in the posterior than the anterior vaginal wall (Jean-Charles C et al. 2010).

There is an increasing amount of published literature on the aetiology of POP explored with the use of sophisticated imaging modalities. Dynamic MRI studies have demonstrated disruptions to the levator ani attachments after vaginal childbirth resulting in POP (Ashton-Miller JA and Delancey JO 2009). Three-dimensional ultrasound imaging has helped in depicting levator ani muscle injury postpartum. “Avulsion injury” of the puborectalis has been associated with significant prolapse, mainly in the anterior and central vaginal compartments (Dietz H and Steensma A 2006). Furthermore, studies involving remodelling of the pelvic floor geometrical changes during childbirth have calculated the maximum stretch of the pelvic floor muscles during the second stage of labour, concluding that a stretch ratio of 1.63 results in muscle injury (Parente MP et al. 2008). Such injuries could only partly account for the loss of pelvic visceral support, as the contribution of vaginal tissue and pelvic fascia is also of paramount importance (Takano CC et al. 2002).

With regard to the urinary continence mechanism, studies have highlighted various contributing pelvic factors, such as the contraction of smooth and striated muscles within the urethral wall, normal vascular plexi, and intact ligaments and fascia supporting the bladder and urethra in their optimal position during an increase in abdominal pressure (Howard D et al. 2000, Ashton-Miller J et al. 2001).

There is still comparatively scant information in the literature, however, about the role of the pelvic floor biomechanics in the pathophysiology of pelvic floor
disorders. Changes in connective tissue content have been linked with POP and SUI (Norton P et al. 1992, Liapis A et al. 2000). Such altered morphologic features in the pelvic support tissue have so far been demonstrated only in histological studies, but the recently proven reliability and validity of transvaginal ultrasound in assessing vaginal wall thickness now offers a new tool for enhanced in vivo studying of the mechanical properties of the pelvic floor complex (Panayi DC et al. 2010). Characterisation of vaginal tissue along with the deformation properties of the levator hiatus in vivo, in real time, can be of great value to better comprehending the mechanics of pelvic floor dysfunction in women.

There are several strengths to the present study. We have demonstrated the feasibility and reliability of studying the strain of the pelvic floor in vivo with real-time ultrasound imaging, using the deformation of the levator hiatus as a surrogate marker. The deformation curve of the levator hiatus is produced by quantifying the gradual increase in abdominal load during Valsalva effort. Differences in the compliance of the LH according to the degree of prolapse were also demonstrated by using a non-invasive tool in a clinical setting. A few limitations are also acknowledged. There were no controls in the present study, which may have confounded our results, given that the compliance of the supportive structure comprised by the levator ani muscle and endopelvic fascia is reportedly considerably different in asymptomatic women (Ashton-Miller JA et al. 2007). In addition, calculation of the levator hiatal deformation was conducted based on the presumption that the pubovisceral muscle strain represents the pubovisceral muscle elasticity, given the relatively small loads applied during Valsalva effort (Greenleaf JF et al. 2003). A more precise approach to studying the biomechanics of the pelvic floor would involve taking into consideration both the mechanical and structural properties of such complex tissues. In order to achieve this, employment of the finite element
method would result in accurately analysing the strain of the pelvic floor under any condition. Such an approach would better adapt to the behaviour of the biological properties of the LAM and endopelvic fascia, especially when greater deformation of the LH is developed (Rubod C et al. 2008, Da Silva-Filho AL et al. 2010). Lastly, due to inherent restrictions of a purely clinical ultrasound study, we did not measure the pelvic floor muscle isometric contractile properties, which would have provided a more precise model of the mechanical behaviour of the pelvic floor under stress.

In conclusion, the present study offers an in vivo, real-time assessment of the deformation properties of the female pelvic floor with the use of 3D/4D translabial ultrasound. The non-linear response of the LAM under gradually increased abdominal load is confirmed by using a non-invasive technique. Understanding the biomechanical properties of the pelvic floor in women with and without symptoms of PFD can enhance our knowledge of the mechanism of POP and SUI. More importantly, as 3D/4D ultrasound imaging becomes increasingly available in clinical settings, more confirmatory studies of the role of this modality in the diagnosis of pelvic floor dysfunction are warranted so as to enhance its clinical role.
CHAPTER 5

Validation of 3D translabial ultrasound measurement of the female urethral sphincter
Chapter 5: Validation of 3D translabial ultrasound measurement of the female urethral sphincter

5.1 Summary

Objective: The aim of the study was to assess the interobserver and intraobserver reliability of translabial 3D ultrasound imaging of the urethral sphincter in non-pregnant nulliparous asymptomatic women.

Study design: Thirty-seven nulliparous asymptomatic women were assessed using 3D translabial ultrasound. Urethral sphincter parameters were measured by the same experienced clinician 2 weeks apart in order to assess the intraobserver reliability. Multiple axial cross-sectional areas at 1-mm distances were used to calculate urethral sphincter volumes. The same measurements were carried out by a second experienced clinician to assess the interobserver reliability.

Results: Excellent intraobserver reliability (interclass correlation coefficient, ICC >0.8) and good interobserver reliability (ICC >0.6) was confirmed.

Conclusions: The described technique of using multiple axial cross-sectional areas at set distances via a translabial approach is a reliable and accurate tool in the evaluation of the female urethral sphincter. It is proposed that this technique is used instead of mathematical formulas as the urethral sphincter is not a uniform geometrical sphere. The technique and values reported may help clinicians in the assessment of women with lower urinary tract disorders.
5.2 Introduction

Urinary incontinence (UI) is a highly prevalent symptom that affects millions of people worldwide of both sexes and all ages. It has been calculated that 8–13% of men and women worldwide and 43–77% of those living in nursing homes are incontinent (Irwin DE et al. 2006). Urinary incontinence imposes a social and emotional burden on the sufferer, adversely affecting women’s physical, psychological and sexual wellbeing (Fultz NH et al. 2004, Wyman JF et al. 1990, Margalith I et al. 2004). It can also substantially decrease health-related quality of life (Papanicolaou S et al. 2005).

Urodynamic stress incontinence represents the commonest cause of incontinence in women, affecting up to 60% of those investigated (Andrada Hamer M et al. 2011). The underlying pathology has been postulated to involve urethral hypermobility, intrinsic urethral sphincter deficiency or any disturbance within the sphincter mechanism (Haliloglu B et al. 2010, Yang JM et al. 2010, Ashton-Miller JA and DeLancey JO 2007).

The urethral sphincter is believed to play an important role in the pathogenesis of lower urinary tract symptoms (LUTS) (Wang HJ et al. 2011), hence information on its structure and function is vital to develop our understanding of urinary incontinence. Currently there are many diagnostic tools available to facilitate functional assessment of the urethra including urodynamics, urethral pressure profilometry, leak point pressures and urethral resistance pressure monitoring. In addition, structural assessment of the female urethra has been made possible with the use of a variety of imaging, implementing 2D, 3D and 4D ultrasound techniques as well as Magnetic Resonance Imaging (MRI).

MRI has been shown to be an accurate tool in identifying urethral anatomy (Tan JL et al. 1998), however costs and time involved in this method are significantly greater in comparison to ultrasound imaging. Ultrasound imaging
may be performed with 2D, 3D and 4D techniques, as well as by using a variety of anatomical approaches such as transanal, translabial and endovaginal. However, each method has its own limitations which need to be carefully considered by the operator.

In particular, 3D ultrasound imaging has been introduced in the last decade as a novel method to evaluate urethral sphincter volumes using an endovaginal or transanal approach (Derpapas A et al 2011). It has been shown to provide a more accurate measurement of urethral sphincter volumes than conventional 2D ultrasound (Derpapas A et al 2011), correlate well with cadaver specimens (Strohbehn K et al 1996) and be regarded as successful and sensitive tool in pregnant women (Toozs-Hobson P et al 2001). Three-dimensional ultrasound imaging of the female urethra has been deemed accurate in evaluating urethral sphincters in both continent and incontinent women (Mitterberger M et al. 2006), while it can serve as a preoperative tool in predicting the outcome of continence surgery (Digesu GA et al 2009).

Although the clinical value of accurately and precisely evaluating the urethral sphincter using 3D ultrasound is evident, its reliability has been poorly studied to date. Hence, the aim of our study was to assess the interobserver and intraobserver reliability of 3D ultrasound imaging of the urethral sphincter in non-pregnant, nulliparous women without LUTS using a translabial approach.

5.3 Methods

Nulliparous women undergoing ultrasound scan for benign gynaecological conditions were recruited from a tertiary referral teaching hospital. All women were given an information sheet about the study, and written consent was obtained. Women were included in the study if they were premonopausal and did not suffer from LUTS. Exclusion criteria also included symptoms of
urogenital prolapse and neurological condition, as well as history of previous continence, pelvic and/or prolapse surgery.

A 3D translabial ultrasound scan of the urethra was performed with women lying supine with their legs abducted and with an empty bladder. A GE Voluson-i system (GE Healthcare, Austria) with a 4-8 MHz transperineal 3D/4D ultrasound transducer (RIC 4–8 RS) was used. If the urethral sphincter was not visualised adequately in its entirety with the surrounding tissue, the scan was repeated. The field of view angle was set to its maximum of 70° in the sagittal plane and volume acquisition angle to 85° in the coronal plane. When a clear image of the urethra and rhabdosphincter was obtained in B-mode, a volume box was placed around the urethra, bladder neck and surrounding tissues, and 3D images were then taken using a slow scan time. The volume box used was 8 cm in length in order to have parallel section increments of less than 0.5 mm. The probe then scanned automatically through an arc of 110° taking 250 images, allowing a simultaneous visualisation of sagittal, transverse and coronal sections. The whole scanning time was 4–6 s and the acquired images were then computer-regenerated into a 3D picture (Figure 5.3.1). In the sagittal plane, the measurements recorded included the distance from the bladder neck to the proximal part of the rhabdosphincter, the bladder neck to the maximal cross-sectional area of the rhabdosphincter and the length of the rhabdosphincter. The cross-sectional area of the total sphincter was serially traced manually, recording each area from one end to the other using 1-mm slice gaps to calculate the area as shown in Figures 5.3.2 and 5.3.3. When the entire sphincter was traced, a volume was computed automatically. The process was repeated for the inner core of the sphincter as showed in Figure 5.3.4. Finally the volume of the inner core was subtracted from the total volume to give a measurement of the rhabdosphincter volume.
All measurements were taken twice by the same clinician 2 weeks apart to assess the intraobserver reliability. A second blinded experienced clinician re-took all measurements in order to assess the interobserver reliability. The interclass correlation coefficient (ICC) was calculated to assess limits of agreement. The scale from Altman was used in classification of the reliability values (Bland JM and Altman DG 1986). ICC values under 0.20 were considered poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good and 0.81–1.00 excellent.

Finally, the urethral sphincter volumes were measured using four different slice gaps between the cross-sectional areas: 1 mm, 2 mm, 3 mm, 4 mm and 8 mm. Each slice gap between cross-sectional areas was measured by using displacement along the median sagittal image. The coefficient of variation was calculated for the urethral sphincter volume measurement, and this was plotted against the different axial cross-section separation. All terms and definitions are in accordance with the latest ICS-IUGA terminology for female pelvic floor dysfunction (Haylen BT et al. 2010).

As the inter-rater reliability of the proposed method has not been previously calculated, the present cohort forms a pilot study and therefore no power calculation was required.

A version 19.0 SPSS statistical package was used for statistical analysis (SPSS version 19.0, Chicago, IL). Local ethical approval was obtained for this study from the London–Surrey Borders Research Ethics Committee (10/H0806/21).
Figure 5.3.1 Three-dimensional translabial image of the female urethra. The volume measurements of the core sphincter and total sphincter were taken in the axial plane (bottom left). (B: bladder, IC: inner core, U: urethra lumen, RS: rhabdosphincter)

Figure 5.3.2 Three-dimensional translabial image of the female urethra showing the cross-sectional area of one of the urethral sphincter slices traced manually (bottom left).
Figure 5.3.3 Multiple-shaded cross-sectional areas of the urethral sphincter measured by tracing the outline of the urethral sphincter at 1-mm intervals. The volume is computed from the cross-sectional areas multiplied by the slice gap of 1 mm.

Figure 5.3.4 Three-dimensional translabial image of the female urethra showing the cross-sectional area of one of the inner core slices traced manually (bottom left).
5.4 Results

The study was conducted on thirty-seven asymptomatic nulliparous women (mean age 37 years old, range 24–48). Twenty-three women were white and 14 were black. The mean age ± standard deviation was 34.8 ± 6.0 vs. 37.5 ± 8.1, respectively (p=0.31). Although black women weighed more than white women on average (mean BMI ± SD for black women was 26.5 ± 3.1 vs. 24.9 ± 3.8 for white women), this difference was not statistically significant (p=0.16).

Table 5.1 shows the urethral sphincter parameters of the study population, as well as the ICC and limits of agreement for measurements taken 2 weeks apart by the same clinician. Excellent intraobserver reliability (ICC >0.8) in the majority of parameters measured by the same clinician on the two separate occasions was demonstrated. More specifically, the ICC value for the total sphincter volumes showed excellent agreement at 0.948, with a mean difference of 0.154 cm³. In regard to the internal sphincter volume, the mean difference between the two measurements was 0.0007 cm³, again representing excellent agreement (ICC=0.993). Measurements of the rhabdosphincter volume, rhabdosphincter length, distance from the bladder neck to proximal rhabdosphincter and distance from the bladder neck to maximal cross-sectional area also showed excellent ICC agreement (ICC=0.985, 0.930, 0.991 and 0.975, respectively).

Table 5.2 shows the ICC and limits of agreement for the same measurements taken by the two investigators. The results show good to excellent interobserver reliability (ICC >0.7) in all parameters measured by the two different clinicians. In addition, the 95% confidence interval for the limits of agreement for all the volume measurements was less than 10% of the mean volumes. This further confirmed the reliability of the measurements.
The coefficient of variation for a 1-mm slice gap of axial cross-sectional measurement (mean 1.734, ± SD 0.781) was similar to the coefficient of variation for a 2-mm slice gap measurement (mean 1.608, ± SD 0.872), at p>0.05. The coefficient of variation for wider gaps of 4 mm and 8 mm was increased with means of 8.538, ±SD 5.136 and 13.889, ±SD 8.860, respectively.
Table 5.1. Intraobserver reliability of the urethral sphincter parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean (±SD)</th>
<th>5th centile</th>
<th>95th centile</th>
<th>Mean of difference</th>
<th>95% Limits of agreement</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSV (cm³)</td>
<td>5.7 (1.4)</td>
<td>3.6</td>
<td>8.8</td>
<td>0.154</td>
<td>0.898</td>
<td>0.973</td>
</tr>
<tr>
<td>ISV (cm³)</td>
<td>0.4 (0.2)</td>
<td>0.2</td>
<td>0.9</td>
<td>0.007</td>
<td>0.987</td>
<td>0.997</td>
</tr>
<tr>
<td>RSV (cm³)</td>
<td>5.3 (1.4)</td>
<td>3.4</td>
<td>8.5</td>
<td>0.208</td>
<td>0.863</td>
<td>0.972</td>
</tr>
<tr>
<td>UL (cm)</td>
<td>3.8 (4.6)</td>
<td>2.3</td>
<td>6.6</td>
<td>−0.801</td>
<td>−0.863</td>
<td>0.506</td>
</tr>
<tr>
<td>RSL (cm)</td>
<td>1.7 (0.25)</td>
<td>1.4</td>
<td>2.3</td>
<td>0.040</td>
<td>0.864</td>
<td>0.964</td>
</tr>
<tr>
<td>BN–PS (cm)</td>
<td>0.7 (0.2)</td>
<td>0.4</td>
<td>1.1</td>
<td>0.020</td>
<td>0.982</td>
<td>0.995</td>
</tr>
<tr>
<td>BN–MCSA (cm)</td>
<td>1.7 (0.9)</td>
<td>0.9</td>
<td>2.5</td>
<td>−0.027</td>
<td>0.758</td>
<td>0.936</td>
</tr>
</tbody>
</table>

TSV: total sphincter volume, ISV: internal sphincter volume, RSV: rhabdosphincter volume, UL: urethral length, RSL: rhabdosphincter length, BN–PS: distance from the bladder neck to proximal rhabdosphincter, BN–MCSA: distance from the bladder neck to maximal cross-sectional area

Table 5.2 Interobserver reliability of the urethral sphincter parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean of difference</th>
<th>95% Limits of agreement</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sphincter volume (cm³)</td>
<td>0.220</td>
<td>0.561</td>
<td>0.884</td>
</tr>
<tr>
<td>Internal sphincter volume (cm³)</td>
<td>0.438</td>
<td>0.987</td>
<td>0.997</td>
</tr>
<tr>
<td>Rhabdosphincter volume (cm³)</td>
<td>0.218</td>
<td>0.934</td>
<td>0.983</td>
</tr>
<tr>
<td>Urethral length (cm)</td>
<td>−0.052</td>
<td>−0.105</td>
<td>0.625</td>
</tr>
<tr>
<td>Rhabdosphincter length</td>
<td>0.590</td>
<td>0.315</td>
<td>0.818</td>
</tr>
<tr>
<td>Distance from the bladder neck to proximal rhabdosphincter (cm)</td>
<td>−0.078</td>
<td>−0.667</td>
<td>0.958</td>
</tr>
<tr>
<td>Distance from the bladder neck to maximal cross-sectional area (cm)</td>
<td>−0.208</td>
<td>−0.462</td>
<td>0.891</td>
</tr>
</tbody>
</table>
5.5 Discussion

The role of the urethral sphincter in the pathological development of urinary incontinence has been clearly postulated (Toozs-Hobson P et al. 2001, Digesu GA et al. 2009). Although the importance of precise structural assessment of the urethral sphincter is paramount, the task of measuring it accurately has recently been met with conflicting opinions. Evaluation of the rhabdosphincter has been previously reported using MRI and ultrasound imaging with the use of different mathematical formulas to measure its volume (Wieczorek AP et al 2012). However, this has been based upon the presumption that the shape of the urethra in its entirety is similar to that of an ellipse. This is incorrect, as the shape of the urethra is neither elliptical nor spherical; previous histological studies enhanced by 3D reconstruction have demonstrated that the female external urinary sphincter changes from a crescent shape to a horseshoe shape and then again back to a crescent shape beginning from the proximal urethra and continuing distally as the urogenital sphincter covering the vagina (Yucel S and Baskin LS 2004). In view of urethra’s atypical geometric shape, we suggest that mathematical formulas or equations should not be used, since they cannot provide an accurate calculation of the urethral volume. Accordingly, we propose an alternative technique to measure the total urethral and rhabdosphincter volumes in a more precise manner using translabial 3D ultrasound; instead of employing standardised mathematical equations, calculations are made from 1-mm cross-sectional areas at set distances across the whole length of the urethra, thus reducing error in measurements unavoidable with the use of mathematical formulas. Moreover, we propose that measurements of the inner core of the urethra (urethral canal) should also be taken into account and subtracted from the measured total urethral volume when calculating the volume of the rhabdosphincter. This would eliminate
another inherent weakness of using a standardised mathematical formula to assess an atypically geometrical-shaped structure.

In our study, we decided to use a translabial approach to overcome the limitations of transanal, transurethral and endovaginal ultrasound techniques. Transanal ultrasound approach requires an expensive and dedicated transducer, and it is a more uncomfortable and embarrassing test for the woman. Transurethral ultrasound scan compresses the urethra thus altering the appearance of the urethral tissues, mainly the smooth urethral muscle and mucosa (Schaer GN et al. 1998). In the endovaginal approach, although the probe is compressing less on the urethra compared to the transurethral modality, it may still inadvertently compress tissues in order to visualise the urethra lying just anterior to it, which impacts on accurate depiction of structures with similar echogenicity, like the circular smooth and striated urethral muscles (Wise B et al. 1992). The proposed 3D translabial ultrasound scan provides good resolution imaging of the urethra with minimal pressure on local structures and therefore is least likely to alter surrounding anatomy. The measurements were performed with an empty bladder to avoid overestimating the sphincter volume due to rhabdosphincter contraction when the bladder is full (Chaliha C et al. 2005). It has to be noted though that due to images been taken along the midsagittal axis, interpretation of sections lateral to the urethral lumen must be performed with caution, always by simultaneous reference to the axial image.

In this study, we have demonstrated good to excellent interobserver and intraobserver reliability using translabial 3D ultrasound for measuring female urethral indices. It provides both a quick (each scan taking 4–6 seconds) and relatively cheap method of assessment; therefore, it is a practical tool when studying this complex anatomical structure. This is of significant clinical value as until recently, we have relied mainly upon functional assessments of the
urethra. However, with the progression of simple structural assessments (undertaken by accurate imaging techniques), we may be able to combine this information to influence our choice of management and predict surgical outcomes, as has been previously suggested (Digesu GA et al. 2006). In the current validation study we have only shown the normative values of urethral anatomical indices in asymptomatic non-pregnant, nulliparous women. Further research in women with lower urinary tract symptoms is warranted to assess the clinical role of 3D imaging of the urethral sphincter.

In conclusion, the potential for accurate assessment of the female urethral morphology with 3D ultrasound is evident and supported by the excellent interobserver and intraobserver reliability demonstrated in this study. We have shown that translabial 3D ultrasound imaging using multiple axial cross-sectional areas at set distances is a reliable and accurate tool in the evaluation of the female urethral sphincter volume. The described technique should be used instead of mathematical formulas as the sphincter is not a uniform geometrical sphere. 3D ultrasound imaging is gaining an increasingly prominent role in urogynaecology; its use as an accurate structural assessment tool could add complementary information to the functional assessment of the urethra gained from established urodynamic studies. The clinical role of 3D ultrasound in assessing women with urethral dysfunction remains to be established through well-designed observational case control studies.
CHAPTER 6

Three-dimensional translabial ultrasound assessment of differences in urethral and pelvic floor morphology among different racial groups
Chapter 6: Three-dimensional translabial ultrasound assessment of differences in urethral and pelvic floor morphology among different racial groups

6.1 Summary

Objective: To compare the urethral sphincter morphology and levator hiatal dimensions between white and black premenopausal nulliparous asymptomatic women using 3D/4D translabial ultrasonography.

Study design: Nulliparous black and white women were recruited in a tertiary gynaecological centre. All women were completely asymptomatic for pelvic floor dysfunction. Women were assessed with 3D/4D translabial ultrasound scan of the pelvic floor, at rest. Measurements of the total urethral sphincter volume (TSV), rhabdosphincter volume, (RSV) and levator hiatal dimensions (LH) were taken at rest, after voiding.

Results: Twenty-three white and 14 black women (37 in total) were investigated. Subjects did not differ by age or body mass index (BMI). Black women were found to have significantly larger rhabdosphincters (RS) than their white counterparts (8.88 cm³ ± 1.65 vs. 5.97 cm³ ± 1.82, respectively, P=0.000). With respect to levator hiatal dimensions, black women had a significantly wider transverse diameter (LHt) at rest than white women (mean difference of LHt=0.43 cm, 95% CI 0.08–0.78, P < 0.05).

Conclusions: Asymptomatic black nulliparous women have significantly larger rhabdosphincters than their white counterparts. Racial differences in the female urethral and pelvic floor morphology could provide an insight on the pathophysiology of pelvic floor dysfunction.
6.2 Introduction

Urinary incontinence (UI) affects up to 50% of women of the general population. The lower urinary tract symptoms and underlying pathology vary in prevalence depending on the population studied and definitions used (Burgio KL et al. 1991, Diokno AC et al. 1986, Nygaard I et al. 2008). The etiological factors contributing to the different types of urinary incontinence are many and do not have a specific association to an individual urinary symptom. Most of the data used to identify risk factors for UI are extrapolated from epidemiological studies, mostly derived from Caucasian populations. However, a few recent studies have examined the difference in prevalence, frequency and severity of urinary incontinence types between different races (Thom DH et al. 2006, Bump RC 1993, DeLancey JO et al. 2010). Bump RC reported that Caucasian women have urodynamic stress incontinence 2.3 times more often than African American women (95% CI 1.4–4.0). In a larger cohort (EPI Study), comprising 1922 black and 892 white women, Fenner et al. showed that a larger proportion of white women with incontinence (39.2%) reported symptoms only of stress urinary incontinence when compared to black women (25.0%), whereas a larger proportion of black women (23.8%) reported symptoms only of urge incontinence when compared to white women (11.0%) (Fenner DE et al. 2010). Although some of the aforementioned studies have been adequately powered and representative of both racial groups, the evidence that risk factors for UI differ significantly between black and white women has been limited. Race seems to be the most significant predictor of urodynamic stress incontinence and detrusor over activity, among incontinent women of different race, even after confounding for recognized risk factors such as age, parity, obesity, diabetes, and previous hysterectomy (Graham and Mallett 2001).
Stress urinary incontinence (SUI) has been historically attributed to different anatomical findings in the continence mechanism; from bladder neck hypermobility, to loss of urethral support and paravaginal defects (DeLancey JO et al. 2008, Petros PE and Ulmsten UI 1990, Richardson AC et al. 1981). The degree to which various continence mechanism parameters differ between women with and without SUI was evaluated in the ROSE study (DeLancey JO et al. 2008). In this study, maximum urethral closure pressure (MUCP) was the parameter with the greatest difference between those with and without stress urinary incontinence, whereas other parameters related to urethral support, including resting urethral axis and urethrovaginal support (point Aa on POP-q), demonstrated lesser effect sizes.

Ultrasound can be used to image the soft tissues of the lower urinary tract. In particular, two- and three-dimensional ultrasound imaging has been used to assess the volume of the urethral sphincter, as discussed in previous chapters (Athanasiou S et al. 1996, Athanasiou S et al. 1999). This technique was validated by correlating urethral images from cadavers with histological findings (Khullar V et al. 1996, Schaer GN et al. 1998). The benefit of three-dimensional ultrasound is that it allows the ovoid structure of the urethral sphincter to be measured accurately (Toozs-Hobson P et al. 2001, Digesu GA et al. 2012). In addition, 3D ultrasound assessment of the urethral sphincter volume is well correlated with the maximum urethral closure pressure (MUCP), in women in their first pregnancy; however following delivery this relationship is lost (Robinson D et al. 2004). This is an important finding as it underlines the relationship between the structure of rhabdosphincter and its physiological function.

Female urethral sphincter has been shown to have a smaller volume in women with urodynamic stress incontinence compared to continent controls in an ultrasound study (Athanasiou S et al. 1999). It has also been reported that the
urethral sphincter volume decreases significantly after the first delivery, irrespective of the mode, but more so after vaginal delivery than caesarean section (Toozs-Hobson P et al. 2008). Childbirth is a well-known etiological factor for stress urinary incontinence; vaginal delivery is associated with a high risk of developing stress urinary incontinence postpartum and this risk is even greater after multiple deliveries (Foldspang A et al 1992, Rortveit G et al. 2003, Leijonhufvud A et al. 2011). In one of the biggest epidemiological studies in Caucasian population looking at the effect of mode of delivery on urinary incontinence (EPINCOT), women with vaginal deliveries were found to have significantly higher prevalence of stress urinary incontinence than those with caesarean deliveries (Rortveit G et al. 2003). Moreover, the effect of childbirth and mode of delivery on the levator ani morphology has also been studied by various researchers (Toozs-Hobson P et al. 2008, Shek KL and Dietz HP 2009, Leijonhufvud A et al. 2011). These studies have demonstrated that vaginal delivery results in significant increase of the levator hiatal dimensions and this increment is higher in women who sustained defects of the levator ani complex. In contrast, delivery by caesarean section decreased the hiatal area by 6–8%.

Based on this data, we hypothesized that the different prevalence of SUI between black and white women would be attributed to differences in the urethral sphincter or/and levator ani hiatus morphology.

6.3 Methods

This study was conducted jointly in the Departments of Urogynaecology and Gyneacology at St Mary’s Hospital, Imperial College Healthcare NHS Trust. It is a pilot cross-sectional observational study comparing 3D/4D translabial ultrasound images of urethral and pelvic floor morphology in two racial groups.
of nulliparous women: 23 white and 14 black. Women were recruited from general gynecological outpatient clinics, were equal access to diverse ethnic groups is offered. All women were asymptomatic for pelvic floor dysfunction as per the symptoms page of the King’s Health (KHQ) and Prolapse-Quality of Life (P-QoL) questionnaires (Kelleher CJ et al. 1997, Digesu GA et al. 2005). Women were premenopausal and had stage 0 or I pelvic organ prolapse as assessed by the Pelvic Organ Prolapse quantification system (POPQ), performed in supine position after emptying their bladder (Bump RC et al. 1996). Race was self identified by participants and age, height and weight were recorded.

Translabial 3D/4D ultrasound images of the pelvic floor were obtained with women in dorsal lithotomy position. A 3D/4D 4-8 MHz curved array probe (GE Healthcare, Austria) was placed at the introitus allowing acquisition of images of the pelvic floor anatomy in three planes: sagittal, coronal and axial (Figures 6.3.1 and 6.3.2). The main transducer axis was oriented in the mid-sagittal plane and the acquisition angle was set at the transducer’s maximum of 70°. Volumes were acquired at rest, after controlling for the optimal plane by 2D imaging in the mid-sagittal plane and 3D box volume acquisition angle set to 85°.

Biometric indices of the urethra were measured at rest with a comfortably full bladder as previously described by Toozs- Hobson et al. 2001. The urethra was imaged in the sagittal plane to ensure that the entire length was visualized, while care was taken not to distort the urethra with the probe during scanning. A 3D/4D scan was then performed and volumes were analysed off-line at later stage. The limits of the urethra and urethral sphincter were identified cranially and caudally and the length of both the urethra and urethral sphincter were recorded, employing the technique described in Chapter 5 of this thesis; the cross-sectional area of the total sphincter was serially traced, recording each area between the proximal and distal end (1 mm slice interval) using the roller
ball on the ultrasound machine and the area was calculated. The volume of the urethral sphincter was computed automatically after all cross-sections of the entire sphincter had been traced. The above steps were repeated for the hypoechoic core sphincter volume (CSV), which includes the longitudinal smooth muscle and urethral lumen, so as to calculate the volume of the inner core and provide accurate measurements of the rhabdosphincter volume (RSV), given urethra’s atypical geometrical shape. The rhabdosphincter volume (RSV) was calculated by subtracting the core sphincter volume (CSV) from the total sphincter volume (TSV) (Figure 6.3.3).

Biometry of the levator hiatus (LH) was also assessed in all women. Again 3D/4D images were acquired at rest in all three planes with women placed in lithotomy position, after women had voided. Levator hiatus measurements were taken off-line in the axial plane after the plane of minimal hiatal dimensions was identified in the mid-sagittal plane. This plane is defined as the minimal distance between the hyperechogenic infero-posterior margin of the symphysis pubis and the hyperechogenic anterior border of the puborectalis muscle just posterior to the anorectal angle, forming a sling around the rectum (Dietz HP et al. 2005). The area of the levator hiatus (LHarea), as well as the antero-posterior diameter (LHap) and transverse diameter of the LH at the level of the urethra (LHt-u) and the vagina (LHt-v) were measured in the axial plane (Figure 6.3.4).

The SPSS statistical package was used for statistical analysis (SPSS version 19.0, Chicago, IL). Non-parametric Mann–Whitney U tests were applied after review of frequency histograms which demonstrated a non-normal distribution of data. Two-tailed statistical significance was considered at P < 0.05. Ethical approval was obtained for this study from the London-Surrey Borders Research Ethics Committee (10/H0806/21) and all women were consented in writing.
Figure 6.3.1 Placement of 3D transducer on the introitus (A) and schematic representation of the image in the sagittal plane (B) (from Dietz. Pelvic floor ultrasound: a review. Am J Obstet Gynecol 2010)

Figure 6.3.2 Three-dimensional ultrasound scan of the pelvic floor. Images shown in sagittal, coronal and axial planes. (PS, pubic symphysis; B, bladder; V, vagina; U, urethra; A, anal mucosa; ARA, anorectal angle)
Figure 6.3.3 Three-dimensional translabial image of the female urethra. The volume measurements of the core sphincter and total sphincter were taken in the axial plane (bottom left). The urethra lumen is shown clearly in the rendered volume image (bottom right). (*U*, urethra; *UL*, urethra lumen; *RS*, rhabdosphincter)

Figure 6.3.4 Plane of hiatal measurements at rest. The level of minimal hiatal dimensions is seen on the sagittal view (left); white line drawn from posterior margin of the symphysis pubis to the anterior margin of the puborectalis muscle, where it defines the anorectal angle. Antero-posterior diameter *LH*ap and transverse diameter at the level of the vagina (*LH*t-v) and the urethra (*LH*t-u) are measured in the axial plane, at the level of minimal hiatal dimensions (right). *U*, urethra; *V*, vagina; *PR*, puborectalis; *PB*, pubic bone; *ARA*, anorectal angle; *AS*, anal sphincter.
6.4 Results

Thirty-seven premenopausal nulliparous women, asymptomatic for pelvic floor dysfunction, were recruited in total; 23 white and 14 black. Subjects did not differ by age; white women had a mean age ± SD of 34.8 ± 6.0 versus 37.5 ± 8.1 for black women (P=0.31). Although black women had a slightly higher body mass index than white women on average (mean BMI ±SD 26.5 ± 3.1 vs. 24.9 ± 3.8 respectively), this difference was not statistically significant (P=0.16).

With regards to urethral sphincter volumes, black women were found to have significantly higher total sphincter volume (TSV) than white women, with mean TSV ± SD index of 9.08 cm$^3$ ± 1.81 and 6.90 cm$^3$ ± 2.02, respectively (P=0.000). Black women were also found to have significantly larger rhabdonsphincters (RS) than their white counterparts (8.88 cm$^3$ ± 1.65 vs. 5.97 cm$^3$ ± 1.82, respectively, P=0.000).

There was no significant difference in the maximum urethral length (MUL) or the maximum urethral sphincter length (MSL) between the two groups. Table 6.1 shows the values of the sphincter parameters for the two groups.

When the levator hiatal dimensions were considered, the only difference noted between the two groups was in the transverse diameter of the levator hiatus, at rest. Black women had a significantly wider transverse diameter at the maximum cross-section of the vagina in the axial plane than white women (mean difference of LHT-v=0.43 cm (95% CI 0.08–0.78, P < 0.05). Table 6.2 shows the levator hiatal dimensions in the two racial groups.
Table 6.1 Comparison of the urethral parameters between the two racial groups

<table>
<thead>
<tr>
<th>Group</th>
<th>MSL (cm) (mean±SD)</th>
<th>MUL (cm) (mean±SD)</th>
<th>TSV (cm$^3$) (mean±SD)</th>
<th>RSV (cm$^3$) (mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (n=23)</td>
<td>2.41 (0.49)</td>
<td>3.56 (0.42)</td>
<td>6.90 (2.02)</td>
<td>5.97 (1.82)</td>
</tr>
<tr>
<td>Black (n=14)</td>
<td>2.53 (0.52)</td>
<td>3.58 (0.36)</td>
<td>9.08 (1.81)</td>
<td>8.88 (1.65)</td>
</tr>
</tbody>
</table>

P 0.57 0.85 0.000 0.000

*MSL, maximum sphincter length; MUL, maximum urethral length; TSV, total sphincter volume; RSV, rhabdosphincter volume*

Table 6.2. Comparison of the levator hiatal (LH) dimensions between the two racial groups

<table>
<thead>
<tr>
<th>Group</th>
<th>LHarea (cm$^2$) (mean±SD)</th>
<th>LHap (cm) (mean±SD)</th>
<th>LHT-u (cm) (mean±SD)</th>
<th>LHT-v (cm) (mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (n=23)</td>
<td>13.93 (2.51)</td>
<td>5.31 (0.56)</td>
<td>3.57 (0.42)</td>
<td>3.48 (0.64)</td>
</tr>
<tr>
<td>Black (n=14)</td>
<td>14.54 (2.48)</td>
<td>5.71 (0.82)</td>
<td>3.48 (0.47)</td>
<td>3.92 (0.41)</td>
</tr>
</tbody>
</table>

P 0.47 0.12 0.58 0.02

*LHarea, levator hiatal area; LHap, levator hiatal antero-posterior diameter; LHT-u, levator hiatal transverse diameter at the level of the urethra; LHT-v, levator hiatal transverse diameter at the level of the vagina*
6.5. Discussion

This pilot study explores the anatomical background of racial differences in the prevalence of lower urinary tract dysfunction and vaginal prolapse as a consequence of childbirth, with the use of 3D translabial ultrasound. We hypothesised that anatomical differences between women of different race, present prior to childbirth, may predispose to or protect them from lower urinary tract and pelvic floor changes postnatally, leading to urinary incontinence and pelvic organ prolapse.

Our data show that black nulliparous premenopausal asymptomatic women have a larger urethral rhabdosphincter than their Caucasian counterparts. As shown by Toozs-Hobson P et al. 2008, urethral sphincter volume decreases by 8–12% in women following vaginal delivery, whereas in women undergoing elective Caesarean section no decrease in the sphincter volume postnatally is demonstrated. The fact that black nulliparous women have a larger urethral sphincter volume antenatally may protect them to some extent from developing SUI postnatally, as a loss of about 10% in the sphincter volume may not suffice to thin the sphincter to a level compatible with SUI (Athanasiou S et al. 1999). Our results also demonstrated a significantly wider transverse diameter of the levator hiatus in black nulliparous women compared to age- and BMI-matched white nulliparous women. To our knowledge, this is the first study assessing the differences in urethral and levator ani morphology between black and white nulliparous asymptomatic women with the use of translabial 3D pelvic ultrasonography.

Investigators have reported significant differences in the prevalence of pelvic floor dysfunction between racial groups (Thom DH et al. 2006, Bump RC 1993, DeLancey JO et al. 2010, Fenner DE et al. 2010, Graham CA et al. 2001 and Grodstein F et al. 2003). The prevalence of different types of incontinence has
also been studied; white women reported stress incontinence symptoms more commonly than black women, whereas twice as many black women reported symptoms of urgency urinary incontinence as compared to white women (Thom DH et al. 2006, Fenner DE et al. 2010). In the EPI study black women were found to have one-third the odds of developing urgency incontinence in comparison to white women, even after adjusting for multiple risk factors. A study by Hoyte et al. looking at the variation in the levator ani morphology with race by using MRI found that nulliparous black women have an increased muscle bulk and denser attachments of the puborectalis to the arcus tendineus fascia pelvis than white counterparts of similar age and BMI (Hoyte L et al. 2005). These findings along with the observation that the pubic arch was slightly wider in black women, led to the conclusion that levator ani complex in black nulliparous women is more intimately associated with its connective tissue and bony attachments. Our findings with regards to levator ani morphology in the different racial groups suggest that black nulliparous asymptomatic women have a wider levator hiatus in the transverse diameter compared to white counterparts. This could be secondary to a wider pubic arch in these women as previously demonstrated, leading to increased span between the two levator ani attachments to each side of the pubic arch. However, our suggestion is in disagreement with Hoyte’s assertion that a denser levator hiatus in black women could increase tone and therefore lead to a narrower levator ani hiatus. It aslo contradicts with findings from MRI studies which showed an overall smaller pelvic floor area in Afro-American women (Howard D et al. 2000 and Baragi RV et al. 2002). Such group differences in the morphometric characteristics of the levator hiatus between black and white nulliparous women are further complicated by recent conflicting reports on differences in pelvic organ prolapse prevalence between black, white and Asian women (Sears CL et al. 2009, Whitcomb EL et al. 2009).
Although all the epidemiological studies performed to date converge to a lower prevalence of stress urinary incontinence in black women compared to white women, there is conflicting data as to which factors contribute to this difference. As early as 1975, Knobel concluded that the lower prevalence of SUI in black South African women in comparison to Asian Indian women, of similar age and parity, was due to higher bladder necks, longer urethras, higher intraurethral resistance and higher pelvic floor contractile force in the former group (Knobel J 1975). Knobel conducted his comparison study with the use of cinefluorocysto-urethrography, perineometry and cystometry. More recent researchers however, attributed the lower prevalence of SUI in black women to a higher maximum urethral closure pressure (Bump RC. 1993, Graham CA and Mallett VT 2001). No significant racial differences were established in those functional studies when mixed urinary incontinence was considered, despite the higher incidence of detrusor overactivity in the white Caucasian population.

Another attempt to identify potential etiological factors for the difference in the prevalence of SUI between racial groups was made through studies using MRI imaging combined with functional tests of the urethra and the pelvic floor in nulliparous women (Howard D et al 2000). Results from that particular study showed that young nulliparous black women had larger urethral volume and significantly higher urethral closure pressures during contraction of their pelvic floor muscles. The authors speculated that these findings could be attributed to a greater bulk or a higher density of urethral striated muscle in black women, which would be consistent with their higher appendicular skeletal mass when compared to that of their white counterparts (Cohn SH et al 1977, Gasperino JA et al. 1995). The same authors reported that black nulliparous women were found to have 17% greater levator ani muscle cross-sectional
area and 24% greater pelvic floor muscle strength, although these differences did not reach a statistical significance.

Our findings with regards to the urethral morphology corroborate with those of previous investigators (Bump RC 1993, Howard D et al. 2000, Graham CA et al. 2001), suggesting that biological differences in the continence mechanism between black and white women could explain, perhaps to a certain extent, the different prevalence of SUI in the two groups. Moreover, our results may imply that a larger urethral volume antenatally offers some protection against birth related trauma, a well established risk factor for developing SUI (Rortveit G et al. 2003). Reduction in both mean urethral sphincter volume and MUCP postpartum, irrespective of the mode of delivery was shown in a combined anatomical and functional study (Robinson D et al. 2004). In the antenatal period, a positive correlation between urethral pressure and urethral sphincter volume was noted; however in the short-term follow up after delivery this correlation was lost. However, a strong association between reduction in MUCP and functional urethral length and development of SUI in both the antenatal period and postnatally was established in very early studies (Iosif S and Ulmsten U 1981). More recent studies confirmed this association showing a significant reduction in the total urethral sphincter volume postpartum by 8–12%, irrespective of the mode of delivery, which persisted 6 months after delivery (Toozs-Hobson P et al. 2008). Although the same trend was noted for the rhabdosphincter volume, the difference between antenatal and postnatal volumes in both groups (vaginal delivery and caesarean section) did not reach significant levels. The authors speculated that the difference between antenatal and postnatal total urethral sphincter volumes possibly represents differences in tissue characteristics as a result of pregnancy. Similarly, Athanasiou et al. 2003, found that women with SUI had significantly shorter, thinner and smaller-volume rhabdosphincters compared with continent
women, and reported good correlation between urethral sphincter volume and the severity of incontinence assessed by videocystourethrography ($r = -0.65, P = 0.001$).

In conclusion the present study emphasizes on the biological differences of the continence mechanism between different racial groups, by using a reliable non-invasive imaging modality. Better understanding of the pathophysiological mechanism of stress urinary incontinence may lead to more comprehensive management pathways. Further anatomical, functional and even histological investigations in different racial groups are needed in order to identify the true role of the urethral sphincter in the continence mechanism.
CHAPTER 7

The use of spiral CT in estimating the prevalence of pubovisceral muscle avulsion in women
Chapter 7: The use of spiral CT in estimating the prevalence of pubovisceral muscle avulsion in women

7.1 Summary

Objective: To calculate the prevalence of pubovisceral muscle (PM) avulsion in a cohort of women presenting at a university hospital for non-urogynecological conditions.

Study design: Women with and without symptoms of PFD were studied in a tertiary referral urogynecology centre between February and October 2010. Women were recruited from the Department of Radiology, where they were referred for a CT pelvis scan due to various pathologies. Assessment of participants included a detailed clinical interview, completion of King’s Health and Prolapse-Quality of Life (P-QOL) questionnaires and spiral CT scan of the pelvis. Bilateral attachments of the pubovisceral muscle (PM) to the pubic rami were identified in the plane of minimal hiatal dimensions, when present, and measurement of the levator symphysis gap (LSG) was taken in cases with PV complete detachment. Bivariate analysis between the PM maximum thickness and different obstetric variables was performed by using Spearman’s correlation test (P < 0.05).

Results: One hundred and ten women were included in the analysis. The overall prevalence of PM avulsion was 6.4% (7/110). In cases with confirmed avulsion, the levator symphysis gap (LSG) ranged from 17.30 to 25.40 mm. The left PM was found to be significantly thinner in parous women and in those with a history of prolonged second stage of labour.
Conclusions: The prevalence of pubovisceral muscle avulsion using spiral CT of the pelvis in a general gynecology cohort is 6.4%. Thinning of the pubovisceral muscle occurs with parity and protracted labour and is more prominent on the left portion of the muscle.
7.2 Introduction

In the last decade childbirth-related injuries of the levator ani muscle (LAM) complex have been under the spotlight of research investigating the aetiology of pelvic floor dysfunction using a number of imaging modalities. With the use of dynamic imaging such as pelvic MRI and 3D–4D translabial ultrasound, researchers have linked LAM trauma with pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Although vaginal delivery has been well established as a significant risk factor for subsequent development of pelvic floor dysfunction in the long-term (Viktrup L et al. 1992, Skoner MM et al. 1994, Mant J et al. 1997), the type and incidence of birth-related pelvic floor injury leading to pelvic floor dysfunction is still controversial.

Levator ani muscle injuries involving both the pubovisceral and the iliococcygeus muscles were demonstrated in 20% of parous women, whereas no such injuries were seen in nulliparous women used as controls. In the same study, women with SUI symptoms were twice as likely to have sustained LAM injury in comparison to continent women (Delancey JO et al. 2003). Levator ani muscle defects have also been reported in parous women with or without symptoms of pelvic organ prolapse. In a comparison study between symptomatic and asymptomatic women, DeLancey reported major injuries of the LAM in 55% of women with POP and in 15.6% of controls (DeLancey JO et al. 2007). Although admittedly case–control studies do not allow for an estimation of the prevalence of LAM trauma in the general population, the authors pointed at several obstetric risk factors that confer an increased risk of POP later in a woman’s life. The etiological link between LAM trauma and POP was further enhanced by Dietz and Simpson in a big cohort study with the use of 3D–4D translabial ultrasound. The authors reported a unilateral or bilateral avulsed puborectalis muscle in 23% of women with significant prolapse (POP-Q.
stage II or higher), whereas only 11% of women without prolapse demonstrated such defects (Dietz H and Simpson J 2008).

Depiction of LAM injuries varies significantly among different imaging modalities. By using 11-Proton density T-2 weighted scans and two-dimensional (2D) fast-spin proton density MRI scans at 5 mm intervals, Margulies and co-authors demonstrated five subdivisions of the LAM in living women; the puboanal, puboperineal, and pubovaginal muscles, which form a single mass in some regions (otherwise known as pubococcygeus or pubovisceral muscle) and have different insertion points, as well as the puborectalis and the iliococcygeal muscles, which can be depicted as distinct subdivisions of the LAM in the axial, coronal, and sagittal planes (Margulies RU et al. 2006). Based on this anatomic configuration, DeLancey et al. 2007 used a muscle injury grading system on MRI to classify LAM defects as minor or major. With the advent of powerful 3D–4D ultrasound imaging which allows volume data set acquisition, identification of LAM injury became readily achievable. Dietz and Lanzarone introduced the term “avulsion” to characterize the loss of continuity between the pubovisceral and puborectalis muscles and the pelvic sidewall in all volume data sets (Dietz HP, Lanzarone V 2005). In a more recent study by the same group, it was proposed that an abnormality in the three central slices on tomographic ultrasound imaging would suffice to set the diagnosis of complete avulsion of the puborectalis muscle (Dietz HP et al. 2011). Furthermore, it has been suggested that an avulsed puborectalis muscle can also be diagnosed by reference to the render volumes of the pelvic floor and that there is very good agreement between the two ultrasound methods in diagnosing avulsion with findings on digital palpation (Dietz HP et al. 2012).

Morphometric characteristics of the LAM such as muscle thickness and volume show great variability in imaging studies due to age- and hormonal status-related muscle atrophy (Dietz H and Steensma A 2006, Hoyte L and Ratiu P
Furthermore, the previously reported high prevalence of LAM injury or avulsion come from studies in women presenting with symptoms of pelvic floor dysfunction and thus might introduce selection bias which can only lead to inferences about the prevalence of LAM injuries in the general population. Therefore with the present study we aim to identify the prevalence of pubovisceral muscle (PM) avulsion in women presenting for spiral CT scan of the pelvis due to non-urogynecological conditions. Spiral CT of the pelvis provides detailed anatomical images with high spatial resolution and acquisition of continuous volumes without slice gaps. The capability of spiral CT to provide accurate assessment of the contour of the LAM and generate images of the pelvic anatomy in multiple planes has been established (Pannu HK et al. 2003).

7.3 Methods

Women with or without symptoms of PFD were studied jointly in the Departments of Urogynaecology and Radiology at St Mary’s Hospital, Imperial College Healthcare NHS Trust. Women were recruited from the Department of Radiology, where they were referred for a CT pelvis scan due to various pathologies. Recruitment eligibility criteria were: female patients referred for CT of the pelvis due to medical indications other than pelvic floor dysfunction (PFD), age over 18 years, ability to give written informed consent for participation in the study. Women without sufficient use of English language or women who had had their previous obstetric care at different hospitals were excluded from the study, as access to maternity records was not feasible.

Assessment of participants included a detailed clinical interview and completion of King’s Health and Prolapse-Quality of Life (P-QOL) questionnaires. Maternity on-line records were searched to cross-check details
of obstetric history. All women underwent spiral CT scan of the pelvis from the level of the iliac crest to 3 cm below the level of the symphysis pubis. This comprised a slight modification of the standard CT pelvis protocol so as to ensure capture of the PM attachment to the pubic ramus. Axial images were generated, and multiplanar reformatting and 3D volume rendering of the data, with 1 mm slice thickness without gaps, were performed for interpretation. Measurements of the maximum thickness of the PM were taken at the level of mid-urethra, in the para-axial plane defined by the line connecting the inferior most borders of the symphysis pubis and the anorectal angle. This reference level, drawn in the sagittal plane, corresponds to the plane of minimal hiatal dimensions as previously described in ultrasound studies (Dietz HP et al. 2011). Bilateral attachments of the PM to the pubic rami were identified, when present, in the same plane and at the same reference level (Fig. 7.3.1), whereas measurement of the levator symphysis gap (LSG) was taken in cases with PM complete detachment (Fig. 7.3.2). The difference in maximum thickness of the PM at the level of mid urethra in women with and without POP was compared by using Mann–Whitney U-test. Bivariate analysis between the PM maximum thickness and various obstetric variables was performed by using Spearman’s correlation test (P < 0.05). We calculated that, based on previous studies using other imaging modalities, a minimum sample of 92 patients would be needed in order to detect a 10% difference between avulsed and non-avulsed PM attachments, with a statistical power of 0.8 and a significance level of 0.05. The present study constitutes a cross-sectional observational study adherent to STROBE initiative principles (Von Elm E et al. 2008).

Ethical approval was granted by the London—Surrey Borders Research Ethics Committee (10/H0806/21) and all participants signed a consent form.
7.4 Results

One hundred and thirteen women were recruited in total. Three data sets were excluded from further analysis due to inadequate depiction of the PM. Mean age was 61 (SD, ± 15) and median parity was 2 (range, 0–10). Twenty-eight women (24.7%) were nulliparous, whereas 69% of women had had more than two deliveries. Almost 92% of parous women had delivered only vaginally and nearly 8% had delivered either by caesarean section exclusively or had experienced both modes of delivery. Nearly one in two (48.2%) parous women had experienced protracted labour at least once, with second stage lasting for more than 2 hr. With regards to symptoms of pelvic floor dysfunction, 15 (13%) women reported prolapse symptoms, whereas 15% of the total participants had undergone previous prolapse repair or continence procedure. Table 7.1 shows the median and 95% Confidence Interval of the PQOL domain scores of women with and without reported symptoms of pelvic organ prolapse (Mann–Whitney U-test, P < 0.001 for all domains).

Overall, 7/110 (6.4%) cases with complete detachment (avulsion) of the PM from the pubic rami were identified, 4 unilateral and 3 bilateral. All cases of avulsion were noted in women with at least one vaginal delivery in their history. There were no cases of either unilateral or bilateral avulsions among nulliparous women. There was no significant relationship between the presence of avulsion and reported symptoms of prolapse. In cases with confirmed avulsion, the levator symphysis gap (LSG) ranged from 17.30 to 25.40 mm. In cases with intact muscle bilaterally, the mean distance between the right and left muscle attachment to the symphysis pubis was 21.2 mm (12.90–30.70) and 22.5 mm (11.5–29.2), respectively. This distance did not differ significantly on either the right or left attachment between women with and without POP symptoms (Table 7.2).
When the maximum thickness of the PM at the level of the mid urethra was considered, the left portion of the muscle was found to be significantly thinner in parous women and in those with a prolonged second stage of labour (duration ≥ 2 hr). This association was not evident however for the right part of the muscle (Table 7.3). The bivariate analysis did not reveal a significant relationship between the PM maximum thickness and the other obstetric parameters, namely age at first delivery, mode of delivery, birth weight and significant vaginal tears.
Figure 7.3.1. Axial view of CT multiplanar 3-dimensional data volume, with 1 mm slice thickness without gaps, showing an intact pubovisceral muscle arising from the body of the pubic bone and forming a sling around the rectum (U: urethra, V: vagina, R: rectum, PM: pubovisceral muscle, PR: puborectalis muscle).

Figure 7.3.2. Axial view of CT scan of a woman with bilateral detachment of the pubovisceral muscle. Measurement of levator symphysis gap (LSG) is denoted bilaterally (U: urethra, V: vagina, R: rectum, PM: pubovisceral muscle).
<table>
<thead>
<tr>
<th></th>
<th>Asymptomatic n=95</th>
<th>Symptomatic n=15</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Health</strong></td>
<td>25 (25-50)</td>
<td>50 (50-50)</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Prolapse impact</strong></td>
<td>0 (0-0)</td>
<td>80 (40-100)</td>
<td>0.0005</td>
</tr>
<tr>
<td><strong>Role limitation</strong></td>
<td>0 (0-0)</td>
<td>66 (40-66)</td>
<td>0.0003</td>
</tr>
<tr>
<td><strong>Physical limitation</strong></td>
<td>0 (0-0)</td>
<td>67 (33-83)</td>
<td>0.0003</td>
</tr>
<tr>
<td><strong>Social limitation</strong></td>
<td>0 (0-0)</td>
<td>55 (22-55)</td>
<td>0.0002</td>
</tr>
<tr>
<td><strong>Personal relationship</strong></td>
<td>0 (0-0)</td>
<td>67 (38-100)</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Emotion</strong></td>
<td>0 (0-0)</td>
<td>56 (45-78)</td>
<td>0.0002</td>
</tr>
<tr>
<td><strong>Sleep energy</strong></td>
<td>0 (0-17)</td>
<td>0 (0-19)</td>
<td>0.23</td>
</tr>
<tr>
<td><strong>Severity Measures</strong></td>
<td>0 (0-0)</td>
<td>41 (33-50)</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

**TABLE 7.1.** Median values (and 95% Confidence Interval) of the PQOL domain scores of asymptomatic and symptomatic women for prolapse (Mann–Whitney U-test, P < 0.001 for all domains).
### TABLE 7.2

<table>
<thead>
<tr>
<th>POP symptoms</th>
<th>Mean difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>21.3</td>
<td>21.2</td>
</tr>
<tr>
<td>no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RDFS: right distance from symphysis pubis, LDFS: left distance from symphysis pubis

### TABLE 7.3

<table>
<thead>
<tr>
<th>NULLIPAROUS mm (SD)</th>
<th>PAROUS mm (SD)</th>
<th>p</th>
<th>DURATION OF 2ND STAGE mm (SD)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt;2h</td>
<td>≥2h</td>
</tr>
<tr>
<td>Rthickmax</td>
<td>5.42 (±1.74)</td>
<td>4.99 (±1.37)</td>
<td>0.24</td>
<td>5.23 (±1.67)</td>
</tr>
<tr>
<td>Lthickmax</td>
<td>5.38 (±1.23)</td>
<td>4.82 (±1.13)</td>
<td>0.03</td>
<td>5.22 (±1.15)</td>
</tr>
</tbody>
</table>

TABLE 7.3. Maximum thickness of the pubovisceral muscle at the level of mid-urethra according to parity and duration of second stage of labour (Mann–Whitney U-test, P < 0.05)
7.5 Discussion

The prevalence of pubovisceral muscle (PM) avulsion in a general gynecology cohort diagnosed by spiral CT was 6.4%. There were no cases of avulsion amongst nulliparous women. The mean values for the distance of the pubovisceral muscle attachment from the symphysis pubis bilaterally as well as the median values of the levator symphysis gap (LSG), in cases with avulsion, have been defined. The left portion of the PM was found to be significantly thinner in parous women and even more so in those who had experienced a prolonged second stage of labour.

Computed tomography is not routinely recommended for depiction of pelvic floor disorders mainly due to irradiation and moderate soft tissue contrast. Despite not being the preferred modality, multiplanar spiral CT can improve visualization and increase diagnostic accuracy in pelvic floor anatomical disorders. Depiction of the soft tissues can be further enhanced with 3D reconstruction of the axial images (Beyersdorff D et al. 2001, Yitta S et al. 2009). In the present study, we achieved acquisition of high quality images of both the bony and soft tissue parts of the pelvic floor by reconstructing axial images using 1 mm thick slices without gaps.

The growing knowledge concerning injury to the portion of the LAM that is attached to the pubic bone has led researchers to employ sophisticated imaging modalities such as MRI and 3D ultrasound in searching for signs of birth related trauma in women with pelvic organ prolapse (Delancey JO et al. 2003, Dietz HP and Simpson JM 2008). Although, the link between birth related LAM injury and pelvic floor dysfunction is proven, the majority of symptomatic women for pelvic organ prolapse would not have sustained such injury.
Therefore, one would expect that in a general population of both nulliparous and parous women with and without symptoms of pelvic floor dysfunction, the true prevalence of pubovisceral muscle avulsion would be significantly lower than that previously quoted for symptomatic groups only. This is confirmed by our study, which showed that only 6.4% of women undergoing CT spiral scan for non-urogynecological indications had sustained avulsion injury. The difference in the prevalence of PM avulsion amongst various studies could be partly due to the great variability in depiction of LAM morphometry between different modalities. Another explanation could be offered by the fact that birth related injuries may result in an architectural distortion of the pubovisceral muscle attachment to the pubic bone, without necessarily an avulsion (Huebner M et al. 2008). The connective tissue and muscular component of the supportive structures of the pelvic floor are subject to such distortion at the time of extreme loading, such as that of the time of vaginal delivery, and can be erroneously perceived as complete muscle avulsion on imaging. This explanation was further strengthened by a recent cadaveric study, which demonstrated that the imaged appearance of an avulsion can be deceptive as it is likely to represent axial resolution artefacts owing to the inherent inability of the ultrasound to resolve thinner pubovisceral attachment sites (Da Silva A. et al 2014).

Several obstetric parameters have been associated with a higher risk of LAM injury. Kearney and co-authors (Kearney R et al. 2006) have demonstrated that forceps delivery and episiotomy confer a significantly higher-risk of LAM injury. Such findings contradict with those from earlier studies showing that controlled forceps delivery reduces the risk of LAM injury by threefold (Gainey HL 1995). Ventouse delivery does not seem to be severely traumatic to the LAM, whereas the impact of episiotomy remains equivocal (Kearney R et al. 2006). Prolonged second stage of labour (≥2 hr) seems to be the single most
important independent risk factor for LAM injury closely followed by head circumference of the fetus (Gainey HL 1995). Our findings suggest that protracted labour results in thinning of the pubovisceral muscle (part of the LAM) which confirms the theory of muscle fibre loss when the fetal head stretches the perineum for a considerable time.

As stated before, the clinical significance of LAM injury in the pathogenesis of POP remains unclear. The relatively low rate of PM avulsion in our study in a general population suggests that this type of injury may represent only one aspect of birth related injuries that link to pelvic floor dysfunction. Genital and hiatal overdistention, dennervation and loss of paravaginal support are other established contributing factors to POP and SUI (Zhu L et al. 2005, Kruger J et al. 2008). The previously quoted high percentage of avulsion injury in parous women is possibly not representative of the general population due to over sampling of women with symptoms of POP. Future studies that seek to explore the proportion of women who develop LAM injuries will require sampling a large representative population of delivering women. Such research is feasible due to the readily available imaging techniques, however, it would require a standardized reporting methodology so as to minimize variability and maximize consistence among the different modalities.

A few limitations of the present study are acknowledged. Due the very nature of the cohort of women recruited from the Department of Radiology, clinical assessment of pelvic organ prolapse was not feasible and thus an objective measure of vaginal support was not included in the study parameters. Restrictions of the clinical setting were also accountable for the lack of ultrasound assessment of participants’ pelvic floor, which would perhaps have identified inherent differences between the two imaging modalities.

In conclusion, the prevalence of pubovisceral muscle avulsion using spiral CT of the pelvis in a general gynaecology cohort is 6.4%. This rate is lower than in
other studies using different modalities, which calls for further exploration of such variation between different imaging techniques. The levator symphysis gap in cases with avulsed muscle has been measured in the plane of minimal hiatal dimensions. Thinning of the pubovisceral muscle occurs with parity and protracted labour and is more prominent on the left portion of the muscle. Since the majority of women with symptoms of pelvic floor prolapse would not have sustained pubovisceral muscle avulsion injury, further research in linking pelvic floor dysfunction with other types of injury and different pathophysiologic mechanisms is warranted.
CHAPTER 8

The role of three-dimensional/four-dimensional translabial ultrasound of the pelvic floor in assessing the outcome of surgical management of prolapse
Chapter 8: The role of three-dimensional/four dimensional translabial ultrasound of the pelvic floor in assessing the outcome of surgical management of prolapse

8.1 Summary

Objective: To explore the usefulness of 3D/4D translabial ultrasound of the pelvic floor in comparing the objective outcomes of two different surgical techniques of posterior vaginal wall repair in a prospective randomised trial.

Study design: Women with symptomatic posterior vaginal wall prolapse scheduled to undergo posterior vaginal wall prolapse repair were randomised using a block randomisation method to standard posterior colpoperineorrhaphy (SCP) or fascial and vaginal epithelial plication (FEP) of the posterior vaginal wall. All women were studied using a Prolapse Quality of Life (PQOL) questionnaire, the Female Sexual Function Index (FSFI) and the Birmingham Bowel and Urinary Symptoms Questionnaire (BBUSQ-22) preoperatively and at six months follow up. Prolapse stage was assessed using the pelvic organ prolapse quantification system (POPQ) preoperatively and at six-months. Translabial ultrasound of the pelvic floor was also carried out preoperatively and 6 months after surgery in order to measure changes in levator hiatal (LH) and urogenital hiatal (GH) dimensions. Test retest reliability of ultrasonographic GH measurements was conducted in a subgroup of patients. Differences in subjective and objective outcomes, including ultrasonographic measurements, between the two surgical methods postoperatively were analysed. Data analysis for non parametric continuous variables was conducted with Mann-Whitney U test, where as POP-Q measures, questionnaire domain scores and LH and GH measurements, before
and after surgery, were compared in each of the two arms using the Wilcoxon signed rank test.

Results: Twenty-eight women with a mean age of 53 (range 34-79 years) were studied. Equal numbers of participants (14 women) were allocated to the PC and FEP arms. Baseline characteristics including age, parity, BMI, previous pelvic surgery and mean preoperative domain scores in all three questionnaires, as well as mean preoperative POPQ measurements were not significantly different between two study groups (P > 0.05). Nor were significant differences in the hiatal and urogenital hiatal dimensions at rest and at Valsalva noted between the two groups preoperatively.

Postoperatively, women who underwent fascial and vaginal epithelium plication showed better anatomical results at 6 months as compared to those who underwent standard colpoperrineorrhaphy (mean difference in Ap = 1.95 ± 0.66 vs 0.85 ± 0.93, P=0.05, respectively and mean difference in GH = 1.57 ± 0.32 vs 0.80 ± 0.42, P=0.05, respectively). Reduction in the size of both the levator and urogenital hiatus was evident after surgery in both groups, irrespective of the technique employed and was statistically significant in all dimensions at Valsalva as well as in the hiatal area at rest (p<0.05). Moreover, women in the FEP group were shown to have significantly smaller urogenital hiatal area and transverse diameter, both at rest and at valsalva, than those who underwent standard posterior colporrhaphy.

Conclusions: Three-dimensional/four dimensional pelvic floor ultrasound is a valid tool in assessing the anatomical outcome of surgical repair of pelvic organ prolapse. Levator and urogenital hiatal dimensions are significantly reduced following surgical correction of posterior wall prolapse, irrespective of the technique employed.
8.2 Introduction

The prevalence of posterior vaginal wall prolapse ranges from 20 to 76% (Olsen AL et al. 1997). Colorectal surgeons tend to use a transanal or transperineal route for surgically repairing such prolapse, whereas gynaecological surgeons favour a transvaginal approach. Although the most appropriate technique for repairing the posterior vaginal wall prolapse is still debatable, there is level I evidence that the vaginal approach is superior to the transanal approach (Maher C and Baessler K 2006). The advantages of the vaginal approach refer to postoperative improvement in both anatomical and functional indices (Nieminen K et al. 2003). While the transvaginal approach to posterior wall appears superior to the transanal approach, significant variations exist in the literature on the methods of vaginal repair employed by gynaecologists. The traditional levator ani muscle plication, whereby the levator is plicated transversely yields acceptable anatomical outcomes, but is associated with high rate of dyspareunia and even bowel dysfunction (Francis WJA and Jeffcoate TNA 1961, Kahn MA and Stanton SL 1997). Several reports have demonstrated favourable anatomic outcomes from transverse fascial plication over discrete rectovaginal fascia defects as a means of correcting posterior vaginal wall prolapse with simultaneous improvement in bowel and sexual function (Porter WE et al. 1999, Kenton K et al. 1999, Cundiff GW et al. 1998). Anatomical and functional outcomes seem to be even better when midline fascial plication is employed, which has been popularised as standard posterior colporrhaphy (Abramov Y et al. 2005).

The levator ani muscle is thought to play a significant role in the pathogenesis of pelvic organ prolapse (DeLancey JO 2001). Recent advances in pelvic floor ultrasonography have allowed measurement of levator hiatal (LH) dimensions with good reliability and repeatability, introducing a valuable and readily
available tool for researchers and clinicians (Dietz HP et al. 2005, Braekken IH et al. 2008). Good to very good reliability of ultrasound measurements of the LH dimensions at rest has been demonstrated with intraclass correlation coefficient ranging from 0.60-0.72, depending on the index measured (i.e. anteroposterior or transverse diameter, cross sectional area etc). Very good reliability of translabial ultrasound in measuring levator hiatal dimensions at Valsalva manoeuvre has also been shown in both symptomatic and asymptomatic cohorts with demonstrable high correlation of hiatal area with pelvic organ descent (Dietz HP et al. 2005).

Women with prolapse have a significantly larger levator ani hiatal area compared with women of similar age and parity without prolapse as shown in two-dimensional and three-dimensional ultrasonography studies of the pelvic floor (Athanasiou S et al. 2007, Dietz HP et al. 2005, Dietz HP and Steensma AB 2006). Increase in the levator hiatal dimensions is also evident in the anteroposterior and transverse diameter in the axial plane of reference as a result of minor or major injury to the levator ani muscle during childbirth (Dietz HP and Lanzarone V 2005). The larger the levator hiatal dimensions the higher the likelihood of prolapse and the risk of surgery as well as recurrence mainly in the anterior and posterior vaginal compartment (Dietz HP et al 2009, Model A et al. 2009). With regards to the posterior compartment specifically, 3D/4D translabial pelvic floor ultrasound offers valid depiction of rectovaginal fascial defects in the coronal and axial plane and can additionally detect other functional or anatomical abnormalities such as intussusception or rectal prolapse (Konstantinovic ML et al. 2007).

Much earlier studies had demonstrated the correlation of pelvic organ prolapse with increased dimensions of the urogenital hiatus. The size of the urogenital hiatus (GH), as measured during vaginal examination, has been shown to be greater in women with significant prolapse than in those with
normal support (Delancey JO and Hurd WW 1998). Furthermore, the size of
the GH is greater in women with increasingly larger vaginal prolapse and in
those who had failed surgical repairs.
Based on the aforementioned evidence, we hypothesised that 3D/4D
translabial ultrasound of the pelvic floor is a useful tool in comparing the
outcomes of two different surgical techniques of posterior vaginal wall
prolapse repair with respect to changes in LH and GH size in a prospective
randomised trial.

8.3 Methods

Women with symptomatic posterior vaginal wall prolapse scheduled to
undergo surgical repair were randomised using a block randomisation method
to standard posterior colpoperineorrhaphy (SPC) or fascial and vaginal
epithelial plication (FEP) of the posterior vaginal wall. In the SPC group
surgeons would perform a midline fascial plication without involvement of the
levators and a perineorrhaphy where deemed appropriate. The FEP is a
technique employed by surgeons in our unit and consists of an extra layer of
repair following midline fascial plication, whereby the vaginal epithelium is
sutured with a Vicryl 1 in an interrupted fashion, as shown in Figure 8.3.1. The
angle of the vaginal epithelium suture changes according to the amount of
vaginal skin and the distance from the vaginal introitus. The perineal body is
reconstituted using a “Nichol’s suture” with a Vicryl 1 suture and finally a 2-0
Vicryl suture is used to close the perineal skin.
Exclusion criteria included previous surgical repair of prolapse in any
vaginal compartment and inability of patients to follow study requirements
such as completion of questionnaires. A scheduled primary concomitant
prolapse repair procedure in another vaginal compartment was not an
exclusion criterion. All women were asked to complete the Prolapse Quality of Life (PQOL) questionnaire (Digesu GA et al. 2005), Female Sexual Function Index (FSFI) (Rosen R et al. 2000), Bristol stool chart and the Birmingham Bowel and Urinary Symptoms Questionnaire (BBUSQ-22) (Hiller L et al. 2002) preoperatively and at six months follow up. Prolapse stage was assessed using the pelvic organ prolapse quantification system (POPQ) preoperatively and at six-month follow up. Three-/four-dimensional transperineal ultrasound of the pelvic floor was conducted preoperatively and 6 months after surgery in order to measure levator hiatal (LH) and urogenital hiatal (GHus) dimensions. Biometry of the LH dimensions was measured at rest and at Valsalva as per the methodology outlined in Chapter 6. The area of the levator hiatus (LHarea), as well as the antero-posterior diameter (LHap) and transverse diameter at the level of the mid-urethra (LHt-u) were measured in the axial plane (Figure 8.3.2). In addition, the dimensions of the GH in the axial plane were calculated from the same set of images per each patient by reference to a plane defined by the line connecting the inferior most part of the symphysis pubis to the posterior fourchette (level of perineal body). As measurement of the GH by ultrasound has not been validated before, test-retest reliability of the method was performed preoperatively in 10 randomly chosen cases between two assessors, as well as by the same assessor in two different time points. The same parameters as with the LH, were measured for the GH (GHus-area, GHus-ap and GHus-t) both at rest and at Valsalva preoperatively and 6 months postoperatively. Figure 8.3.3 shows the different levels of measurements for the LH and GHus. by translabial pelvic floor ultrasound.
Figure 8.3.1 The fascial and vaginal epithelial plication (FEP) technique for repairing a posterior vaginal wall prolapse. Clockwise from top left picture: Suture passed from inner aspect of right side of vaginal epithelium, brought out and around the apex, then from out in and down to the inner part of the left side to be tied in the middle.
Figure 8.3.2 3D translabial ultrasound of the pelvic floor pre-surgery (left) and 6 months post-surgery (right) at rest of a 53 year-old woman who underwent posterior repair


Figure 8.3.3 Measurements of the levator and urogenital hiatal dimensions by 3D pelvic floor ultrasound at rest on the same set of images. Left: Measurements of levator hiatal indices with the plane of minimal dimensions (yellow line) as reference, Right: Measurements of urogenital hiatal indices at the proposed reference line (plane of perineal body, yellow line). The different planes of measurements can be appreciated better on the midsagittal and coronal images (top left and top right)

Differences in subjective outcomes between the two surgical methods postoperatively were measured in all questionnaire domains. Data analysis for non parametric continuous variables was conducted with Mann-Whitney U test. POP-Q measures, questionnaire domain scores and LH and GH measurements, before and after surgery, were compared in each of the two arms using the Wilcoxon signed rank test.

Local ethical approval was obtained for this study from the London–Surrey Borders Research Ethics Committee (10/H0806/21) and all participants gave written consent. The methodology of the study is in accordance with the CONSORT statement for randomised controlled studies (Schulz KF et al 2010).

8.4 Results

Twenty eight women with a mean age of 53 (range 34-79 years) were studied in total. Equal numbers of participants (13 women) were allocated to the two surgical repair technique arms, after 2 women were excluded for not meeting the inclusion criteria. Two further participants in the standard posterior colporrhaphy (SPC) arm were lost to follow up, whereas 1 participant allocated to the fascial and vaginal epithelial plication (FEP) arm declined follow up assessment with ultrasound and 1 did not attend the follow up study visit, leaving 22 patients for final data analysis (Figure 8.3.4).

Baseline characteristics including age, parity, BMI, previous pelvic surgery and mean preoperative domain scores in all three questionnaires were not significantly different between two study groups (P > 0.05). Nor were the median preoperative POPQ measurements and the levator and urogenital hiatal dimensions at rest and at Valsalva between the two groups preoperatively (Tables 8.1 and 8.2). Concomitant prolapse repair procedures in
the two groups were as follows: 66% anterior colporrhaphy in the SPC group vs 69% in the FEP, 41% hysterectomy ± vault fixation in the SPC group vs 38% in the FEP group, P=0.85

The inter-observer and intra-observer reliability tests showed moderate to very good agreement in all preoperative GH parameters measured by translabial ultrasound with reference to the level of the perineal body (Table 8.3).

Women who underwent fascial and vaginal epithelium plication demonstrated better anatomical support in the posterior vaginal compartment at 6 months in comparison to those who underwent standard colporrhaphy, however the difference was only significant for point Ap (mean difference = 1.95 ± 0.66 vs 0.85 ± 0.93, P=0.05, respectively). Women in the FEP group also demonstrated smaller genital hiatus postoperatively, in comparison to those who underwent standard colporrhaphy (mean difference in GH = 1.57 ± 0.32 vs 0.80 ± 0.42, P=0.05, respectively) (Table 8.4).

Reduction in the size of the levator hiatus was evident after surgery in both groups, irrespective of the method applied. Women in both study arms demonstrated a significantly smaller levator hiatus in the antero-posterior and transverse diameter as well as the area during Valsalva effort, whereas the hiatal area was significant smaller also at rest (Table 8.5). While neither surgical technique showed superiority in the rate of levator hiatal size reduction, women in the FEP arm showed significantly smaller urogenital hiatus than those in the SPC arm as measured by pelvic floor ultrasound. The mean differences in hiatal measurements pre- and postoperatively between the two groups are presented in Table 8.6.

With respect to subjective outcomes, the only significant difference postoperatively between the two groups was a greater improvement in bowel
evacuation in women with fascial and vaginal epithelium plication (mean difference in score -2.01 ± 0.73 vs -1.33 ± 0.73, p=0.03).
Figure 8.3.4 Flow diagram of participants
<table>
<thead>
<tr>
<th></th>
<th>STANDARD COLPORRHAPHY</th>
<th>FASCIAL AND VAGINAL EPITHELIAL Plication</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PREOPERATIVE MEDIAN (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aa</td>
<td>-1.00 (-2.02,-0.53)</td>
<td>-1.00 (-1.82,-0.39)</td>
<td>0.81</td>
</tr>
<tr>
<td>Ba</td>
<td>-2.00 (-2.40,-0.71)</td>
<td>-1.50 (-2.35,-0.21)</td>
<td>0.65</td>
</tr>
<tr>
<td>C</td>
<td>-3.50 (-5.56,-1.22)</td>
<td>-3.00 (-4.65,3.17)</td>
<td>0.30</td>
</tr>
<tr>
<td>Ap</td>
<td>-1.50 (-1.97,-0.70)</td>
<td>-1.00 (-1.61,-0.50)</td>
<td>0.56</td>
</tr>
<tr>
<td>Bp</td>
<td>-2.00 (-2.41,-0.92)</td>
<td>-1.00 (-2.12,-0.77)</td>
<td>0.71</td>
</tr>
<tr>
<td>GH</td>
<td>4.50 (3.55,4.89)</td>
<td>4.00 (3.42,4.58)</td>
<td>0.56</td>
</tr>
<tr>
<td>PB</td>
<td>3.00 (2.42,3.35)</td>
<td>3.00 (2.08,3.47)</td>
<td>0.70</td>
</tr>
<tr>
<td>TVL</td>
<td>8.00 (7.45,8.22)</td>
<td>8.00 (7.42,9.47)</td>
<td>0.35</td>
</tr>
<tr>
<td>D</td>
<td>-5.00 (-7.19,-2.15)</td>
<td>-6.00 (-6.50,3.80)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Table 8.1. Preoperative POPQ measurements expressed as median (95% CI) in the two study arms.

<table>
<thead>
<tr>
<th></th>
<th>STANDARD COLPORRHAPHY</th>
<th>FASCIAL AND VAGINAL EPITHELIAL Plication</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td><strong>PREOPERATIVE MEDIAN (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LHap(r)</td>
<td>5.35 (4.82,5.55)</td>
<td>5.12 (4.85,5.65)</td>
<td>0.90</td>
</tr>
<tr>
<td>LHap(v)</td>
<td>5.76 (5.54,6.13)</td>
<td>6.01 (5.57,6.55)</td>
<td>0.50</td>
</tr>
<tr>
<td>LHt(r)</td>
<td>4.23 (3.91,4.57)</td>
<td>3.94 (3.71,4.21)</td>
<td>0.36</td>
</tr>
<tr>
<td>LHt(v)</td>
<td>4.84 (4.53,5.29)</td>
<td>4.58 (4.05,5.35)</td>
<td>0.60</td>
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<tr>
<td>LHarea(r)</td>
<td>18.14 (16.34,19.34)</td>
<td>17.00 (14.61,21.17)</td>
<td>0.40</td>
</tr>
<tr>
<td>LHarea(v)</td>
<td>21.69 (19.10,24.26)</td>
<td>20.21 (19.42,23.69)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Table 8.2. Preoperative LH dimensions expressed as median (95% CI) in the two study arms.

LHap: anteroposterior diameter of the LH, LHt: transverse diameter of the LH, (r): rest, (v): Valsalva
<table>
<thead>
<tr>
<th></th>
<th>GHus-ap(r)</th>
<th>GHus-t(r)</th>
<th>GHus-area(r)</th>
<th>GHus-ap(v)</th>
<th>GHus-ap(v)</th>
<th>GHus-area(v)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICC-inter</strong></td>
<td>0.73</td>
<td>0.54</td>
<td>0.77</td>
<td>0.79</td>
<td>0.62</td>
<td>0.81</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td>&lt;0.001</td>
<td>&lt;0.05</td>
<td>&lt;0.001</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>ICC-intra</strong></td>
<td>0.76</td>
<td>0.50</td>
<td>0.50</td>
<td>0.84</td>
<td>0.60</td>
<td>0.85</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td>&lt;0.001</td>
<td>&lt;0.05</td>
<td>&lt;0.001</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.001</td>
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</tbody>
</table>

Table 8.3. Inter- and intra-observer reliability tests for the ultrasound measurements of the GHus dimensions at the level of the perineal body preoperatively.


<table>
<thead>
<tr>
<th></th>
<th>STANDARD COLPORRHAPHY</th>
<th>FASCIAL AND VAGINAL EPITHELIAL Plication</th>
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</tr>
</thead>
<tbody>
<tr>
<td>POSTOPERATIVE MEAN DIFFERENCE (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aa</td>
<td>1.35 (0.94)</td>
<td>1.05 (0.79)</td>
<td>0.43</td>
</tr>
<tr>
<td>Ba</td>
<td>0.85 (0.85)</td>
<td>0.95 (0.82)</td>
<td>0.78</td>
</tr>
<tr>
<td>C</td>
<td>1.56 (3.60)</td>
<td>3.61 (5.37)</td>
<td>0.36</td>
</tr>
<tr>
<td>Ap</td>
<td>0.85 (0.93)</td>
<td>1.95 (0.66)</td>
<td>0.05</td>
</tr>
<tr>
<td>Bp</td>
<td>1.01 (0.77)</td>
<td>1.92 (0.39)</td>
<td>0.06</td>
</tr>
<tr>
<td>GH</td>
<td>0.80 (0.42)</td>
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<td>0.05</td>
</tr>
<tr>
<td>PB</td>
<td>-0.55 (0.64)</td>
<td>-0.36 (0.81)</td>
<td>0.56</td>
</tr>
<tr>
<td>TVL</td>
<td>0.55 (1.28)</td>
<td>-0.90 (1.22)</td>
<td>0.25</td>
</tr>
<tr>
<td>D</td>
<td>1.38 (2.72)</td>
<td>1.75 (4.74)</td>
<td>0.84</td>
</tr>
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</table>

Table 8.4. Mean difference and SD in POPQ measurements before and after surgery in the two groups
### Table 8.5

Median values (and range) of levator hialtal dimensions following posterior vaginal wall repair in all women (n=25), irrespective of technique employed

(LHap: anteroposterior diameter of the LH, LHt: transverse diameter of the LH, LHarea: area of the levator hiatus (r): rest, (v): Valsalva)

<table>
<thead>
<tr>
<th></th>
<th>Preoperatively</th>
<th>Postoperatively</th>
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<tbody>
<tr>
<td>LHap(r)</td>
<td>5.23 (4.17-6.18)</td>
<td>5.27 (3.90-6.07)</td>
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<tr>
<td>LHap(v)</td>
<td>5.97 (5.03-7.74)</td>
<td>5.49 (3.99-7.05)</td>
<td>0.05</td>
</tr>
<tr>
<td>LHt(r)</td>
<td>4.00 (3.33-5.12)</td>
<td>4.12 (3.14-5.51)</td>
<td>0.88</td>
</tr>
<tr>
<td>LHt(v)</td>
<td>4.64 (3.23-6.72)</td>
<td>4.30 (3.55-5.84)</td>
<td>0.05</td>
</tr>
<tr>
<td>LHarea(r)</td>
<td>17.22 (13.21-31.60)</td>
<td>15.48 (12.34-21.01)</td>
<td>0.03</td>
</tr>
<tr>
<td>LHarea(v)</td>
<td>21.36 (15.33-29.74)</td>
<td>18.23 (11.65-27.74)</td>
<td>0.01</td>
</tr>
<tr>
<td>Method</td>
<td>LHap(r)</td>
<td>LHap(v)</td>
<td>LHt(r)</td>
</tr>
<tr>
<td>--------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>SPC</td>
<td>0.12(±0.81)</td>
<td>0.35(±0.85)</td>
<td>0.16(±0.51)</td>
</tr>
<tr>
<td>FEP</td>
<td>0.15(±0.81)</td>
<td>0.58(±0.72)</td>
<td>0.21(±0.71)</td>
</tr>
<tr>
<td>P</td>
<td>0.47</td>
<td>0.54</td>
<td>0.21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>GHap(r)</th>
<th>GHap(v)</th>
<th>GHt(r)</th>
<th>GHt(v)</th>
<th>GHarea(r)</th>
<th>GHarea(v)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPC</td>
<td>0.88(±0.81)</td>
<td>0.91(±0.86)</td>
<td>0.25(±0.44)</td>
<td>0.34(±0.15)</td>
<td>2.05(±1.56)</td>
<td>2.09(±1.65)</td>
</tr>
<tr>
<td>FEP</td>
<td>0.92(±0.72)</td>
<td>1.02(±0.75)</td>
<td>0.67(±0.70)</td>
<td>1.05(±0.57)</td>
<td>3.23(±1.81)</td>
<td>3.69(±1.90)</td>
</tr>
<tr>
<td>P</td>
<td>0.14</td>
<td>0.08</td>
<td><strong>0.04</strong></td>
<td><strong>0.01</strong></td>
<td><strong>0.02</strong></td>
<td><strong>0.05</strong></td>
</tr>
</tbody>
</table>

Table 8.6. Mean difference (± SD) of LH and GH dimensions before and after posterior repair in the two arms as measured by translabial pelvic floor ultrasound.

(LHap: anteroposterior diameter of the LH, LHt: transverse diameter of the LH, (r): rest, (v): Valsalva)

(GHap: anteroposterior diameter of the GH, GHt: transverse diameter of the GH, (r): rest, (v): Valsalva)


8.4 Discussion

In the present study two methods of surgical repair of posterior wall prolapse were compared in terms of anatomical outcomes with the use of translabial ultrasound scan of the pelvic floor. Fascial and vaginal epithelial plication of the posterior vaginal wall yielded better anatomical results as demonstrated by POPQ measurements in the posterior compartment and GH at 6 months following surgery, when compared to standard posterior colpoperineorrhaphy. The FEP repair technique also resulted in a significantly smaller urogenital hiatus than the standard colpoperineorrhaphy, as shown by 3D/4D ultrasonography. This is an important finding as Delancey JO and Hurd WW 1998 have shown that a larger urogenital hiatus is associated with recurrence of vaginal prolapse. Despite a prominent reduction in the levator hiatal size at rest and at Valsalva post surgery in all patients, neither technique was superior in terms of rate of reduction of the levator hiatus. Besides the ultrasonographic evaluation of the two surgical techniques, the present study revealed that patients who underwent fascial and vaginal epithelium plication in the posterior compartment demonstrated significantly better improvement in bowel evacuation than their counterparts in the standard colporrhaphy group. This could potentially play an important role in choosing the method of repair for minimising the risk of recurrence, as difficulty in bowel evacuation has been associated with persistent posterior vaginal wall prolapse (Spence-Jones C et al. 1994). None of the other subjective outcome measures (PQOL domain scores, sexual function scores and other bowel symptoms) were significantly different between the two study arms.

A rectocoele or posterior vaginal wall prolapse is thought to be a herniation of the anterior rectal and posterior vaginal wall into the lumen of the vagina, which arises from either a tear or an attenuation of the rectovaginal
(Denonvilliers’) fascia (Shull BL and Bachofen C 1999). Previous studies have reported conflicting evidence with respect to the superiority of different techniques in producing more favourable anatomical and functional outcomes, including sexual and bowel function. Repair of discrete site-specific defects of the rectovaginal fascia has been associated with higher anatomic recurrence rates and similar rates of dyspareunia and bowel symptoms with the standard posterior colporrhaphy with plication of the levator ani muscles (Abramov Y et al.2005). In a more recent randomised control trial evaluating posterior wall prolapse repair techniques with and without mesh augmentation, standard colporrhaphy without midline levator ani plication resulted in similar anatomical and functional outcomes with the site-specific fascial repair technique in 1 year follow up (Paraiso MF et al. 2006). Furthermore, significantly improved symptomatic rectocele and obstructed defecation 24 months after midline rectovaginal fascial plication without levator ani muscle placation were reported in a prospective study (Maher CF et al. 2004). In the latter study the rate of dyspareunia actually improved postoperatively, which, according to the authors, was possibly due to the minimal trimming of vaginal epithelium, which would be similar to the technique employed in the present study. Our results in terms of subjective outcomes corroborate with those of Maher et al 2004, suggesting that utilisation of the vaginal epithelium as an extra layer of reinforcement of the posterior vaginal wall rather than trimming of it may account for the improvement of bowel evacuation in the group of women who underwent fascial and vaginal epithelial plication. Perhaps maintaining more vaginal epithelium during the repair results in better mechanical tissue strength due to alteration of collagen remodelling in favour of the old stronger collagen material (Jackson SR et al. 1996).

To our knowledge, 3D/4D translabial pelvic floor ultrasound has never been used before to compare the anatomical outcomes between two different
techniques for posterior wall prolapse repair. The very existence of the rectovaginal septum (RVS) as a separate, surgically useful structure, is still debatable amongst surgeons and anatomists, perhaps partly because demonstrating the RVS during surgery requires careful dissection of the posterior vaginal wall, preferably with the help of hydrodissection, in order to avoid cutting through it. Arguably, this very technique may too be flawed as the dissection itself can lead to damage of the rectovaginal septum and thus identification of iatrogenic defects in the fascia. Static 3D ultrasound of the posterior vaginal wall does not seem to yield any reproducibly discrete findings regarding the RVS that are associated with posterior compartment prolapse or sonographic rectocele formation (Dietz HP 2011). Hence, our study focused on depicting the reduction in the levator and urogenital hiatal dimensions postoperatively as outcome measures for comparing two surgical techniques for repairing posterior wall defects. The reasoning behind selecting such biometrical indices is dual: firstly, the evidence that levator hiatal overdistension is strongly associated with clinically evident prolapse and prolapse recurrence following rectocele repair (Barry C et al 2006) and secondly DeLancey’s finding that clinically measured enlarged urogenital hiatus is persistent in women with failed prolapse repairs (Delancey JO and Hurd WW 1998). The findings of the present study confirm that surgical repair of posterior wall prolapse results in significantly reduced levator hiatal dimensions irrespective of the technique employed by the surgeons. Perhaps the small size of the sample in our study did not provide sufficient power to demonstrate superiority of either technique in the rate of levator hiatal size reduction postoperatively. Although neither technique involved plication of the levators, the reduction in hiatal size following posterior wall repair is most likely owed to the reinforcement of the rectovaginal fascia which is laterally connected to
the endopelvic fascia, which is intertwined with the levator ani muscles, and inferiorly attached to the perineal body.

More importantly, we have demonstrated that 3D/4D translabial ultrasonography is a useful tool in assisting the clinician evaluate the outcome of surgical management of prolapse by depicting the reduction in the urogenital hiatus postoperatively. By using the level defined by the line connecting the inferior most part of the symphysis pubis to the posterior fourchette (perineal body) as reference for measurements, urogenital hiatal dimensions can be calculated with moderate to very good inter- and intra-reliability rate. Moreover, the postoperative reduction in the GH size as measured by ultrasound was associated with the corresponding improvement in the anatomical improvement as defined by POPQ scores. This was evident even when comparison of the two surgical techniques was explored, with women who underwent fascial and vaginal epithelial plication demonstrating significantly improved Ap scores alongside reduced GH dimensions when compared with women in the standard colporrhaphy group. Bigger reduction in the GH transverse diameter and area in the FEP technique arm could possibly be attributed to the conservation and plication of the excessive vaginal epithelium, which results in approximation of the lateral projections of the endopelvic fascia to the midline.

The present study has several strengths. It constitutes a randomised control trial between two different surgical techniques in women with similar demographic characteristics in both arms. It also utilises both subjective and objective anatomical outcome measures to compare the two techniques, with clear emphasis on the ultrasonographic differences in the two biometric indices that play an important role in recurrence of prolapse and severity of prolapse symptoms. Finally, we introduce a method for measuring the
urogenital hiatus by 3D translabial ultrasound which appears to have good reproducibility.

A few weaknesses are also acknowledged. We did not perform a power calculation as the current served as pilot study for evaluating the use of 3D/4D pelvic floor ultrasound in assessing the outcome of surgical repair for prolapse. We also did not explore the potential correlation of the changes in the hiatal size with symptoms severity, albeit the small size of the study would probably fail to detect such relationship.

In conclusion, in the current study we provide evidence that 3D/4D is a useful tool in evaluating the anatomical outcomes of surgical repair of posterior wall prolapse. Genital and levator hiatal size measurements by ultrasound can be used as anatomical outcome measures in comparing two different surgical techniques. With respect to POPQ measurements and ultrasonographically assessed urogenital size, posterior wall repair by fascial and vaginal epithelial plication yields better results than standard posterior colporrhaphy without midline levator ani muscle plication.
CHAPTER 9

Conclusions and suggestions for future research
9.1 Conclusions

The overall null hypothesis, as stated at the beginning of the thesis, has been rejected as measurable differences in anatomical and functional indices of the lower urinary tract and pelvic floor have been demonstrated with the use of imaging. Three- and four-dimensional translabial pelvic floor ultrasound, in particular, has been shown to be of value in the assessment of women with lower urinary tract symptoms and pelvic organ prolapse. Moreover, spiral CT of the pelvis has been employed to accurately depict the levator ani muscle complex and calculate the prevalence of pubovisceral muscle avulsion in the general female population.

In chapter 4 the application of 3D/4D translabial ultrasound in studying the biomechanics of the female pelvic floor is described. Very good to excellent repeatability in measuring levator hiatal dimensions at rest and at standardised Valsalva manoeuvre is achieved demonstrating a valid method in studying the deformation of the muscle component of the pelvic floor in vivo. The biomechanical study of the pelvic floor with ultrasound corroborates with the results from previous studies on laboratory-based mechanical studies of vaginal tissues that demonstrated a non-linear response to exertion of gradually increased force on the pelvic floor during Valsalva manoeuvre. This deformation, conveyed to the pubovisceralis portion of the levator ani, is uneven at its different anatomical subdivisions; the strain of the pubovisceralis at its most cephalad part (pubourethralis) implies a far less compliant tissue with more prominent viscoelastic properties than in its mid-vaginal portion (pubovaginalis). Furthermore, pelvic floor tissue properties differ in women with prolapse, as revealed by a less compliant pubovisceralis muscle in cases with significant prolapse, again more so in the anterior than in the central vaginal compartment.
In chapter 5 very good to excellent reliability in measuring female urethral indices by 3D ultrasound of the pelvic floor is demonstrated. The translabial approach is described and the advantages of a cheap, valid and reliable method of depicting the rhabdosphincter volume without distorting the surrounding anatomical structures are discussed. Aside from providing normative values for female urethral indices in asymptomatic nulliparous women, the study proposes calculating the rhabdosphincter volume by taking 1-mm cross-sectional areas at set distances across the whole length of the urethra, thus reducing error in measurements, which are unavoidable when mathematical formulas are used based on the presumption that the shape of the urethra is similar to that of an ellipse. Calculation of cross-sectional areas of the urethra from its most proximal to its most distal end and subtraction of the inner core of the urethra (urethral canal) and longitudinal smooth muscle from the measured total urethral volume eliminates the inherent weakness of using a standardised mathematical formula in assessing an irregularly shaped structure. Studying the female urethral morphology with a non-invasive, readily available tool provides a valuable adjunct to the functional assessment of the urethra. Accurate information about both the anatomy and the function of the urethra could be of great value to clinicians in evaluating women with LUTS in both a clinical and research setting.

In chapter 6 the anatomical background of racial differences in the prevalence of lower urinary tract dysfunction is explored with the use of 3D translabial ultrasound. The method employed was the one previously described and test-retested in chapter 5. Black nulliparous premenopausal asymptomatic women have a larger urethral rhabdosphincter than their white counterparts, which may partly account for the lower incidence of stress urinary incontinence in black women reported in epidemiological studies. Findings also suggest that black nulliparous asymptomatic women have a wider levator hiatus in the
transverse diameter compared to their white counterparts. This could be secondary to a wider pubic arch in the former group as previously demonstrated in anatomical studies, leading to increased span between the levator ani attachments to each side of the pubic arch. However, the latter findings contradict with those of other researchers who, by use of MRI, demonstrated a narrower levator hiatus in black women due to increased muscle tone. Such discrepancies in the reported results confirm the recent conflicting evidence about the different prevalence of pelvic organ prolapse between black, white and Asian women.

In chapter 7 the prevalence of pubovisceralis muscle (PM) avulsion in a general gynaecology cohort is calculated with the use of pelvis spiral CT. The overall calculated prevalence is 6.4% with all cases of avulsion being amongst parous women. The mean values for the distance of the PM muscle attachment from the symphysis pubis bilaterally as well as the median values of the levator symphysis gap (LSG), in cases with avulsion, are defined. The left portion of the PM is shown to be significantly thinner in parous women and in those who had experienced a prolonged second stage of labour, which confirms the theory of muscle fibre loss when the fetal head stretches the perineum for a considerable time. Although computed tomography is not routinely recommended for imaging the pelvic floor, mainly due to irradiation and suboptimal soft tissue contrast, multiplanar spiral CT offers accurate depiction of the pelvic floor soft and bony structures by 3D reconstruction of axial images using 1 mm thick slices without gaps. This offers a significant advantage over other imaging modalities in depicting different degrees of architectural distortion of the pubovisceralis muscle, thus significantly limiting artefacts that can be erroneously perceived as complete muscle avulsions.

In chapter 8, 3D/4D translabial ultrasound of the pelvic floor is employed to assess the anatomical outcome of surgical repair of posterior wall prolapse.
Two different surgical techniques are compared in a randomised controlled trial with emphasis on the rate of reduction in levator and urogenital hiatal dimensions postoperatively. Moderate to very good reliability of pelvic floor ultrasound in assessing the urogenital hiatus is demonstrated and the method is proposed as a useful adjunct to clinical evaluation of prolapse with POPQ system. Genital and levator hiatal size assessed ultrasonographically can be used as anatomical outcome measures in comparing two different surgical techniques for posterior wall prolapse repair since their reliability and good correlation with the corresponding POPQ measurements is proven.

9.2 Suggestions for future research

Imaging of the pelvic floor in women with lower urinary tract dysfunction examines various areas of interest such as urethral sphincter volume, urethra and bladder neck morphology, urethral position and mobility, morphology of the vaginal walls in all three compartments, the anal canal and anal sphincter muscle complex, as well as the anatomy and function of the levator ani muscle. Quality of imaging may be influenced by a number of factors such as patient position and habitus, provocation manoeuvres such as Valsalva, as well as operator experience and equipment quality, posing a challenge with regards to standardising reports within the same modality, as well as between different ones.

Validation studies of pelvic floor imaging should be the focus of research in the immediate future. Although researchers have successfully and reliably managed to demonstrate pelvic floor muscle trauma associated with childbirth, its relatively low prevalence has not yet substantiated its causative role in POP. Internal and external validity studies of the various techniques and imaging modalities are warranted; depiction of the same pelvic floor
anatomical indices with transperineal, endovaginal or endoanal ultrasound should be compared with each other and validated against findings from anatomical dissection on cadavers. Moreover, comparison studies between pelvic floor MRI and 3D/4D ultrasound would help validate the methodology for assessing LAM trauma and set the standards of quantification and stratification of defects.

Another area of great interest is that of in vivo biomechanical studies of the pelvic floor during second stage of labour. The forces applied to the pelvic floor by the presenting part of the foetus, in particular during delivery, are admittedly responsible for the injury to the soft tissues; however the exact mechanism of injury remains unknown. Intrapartum translabial ultrasound of the pelvic floor could help distinguish between muscle avulsion injury, indirect minor and major fascial and muscle trauma or delayed denervation injury and thus identify the causative role of childbirth-related pelvic floor trauma in developing pelvic floor dysfunction.

Pelvic floor ultrasound can also be employed in identifying the correct placement of mid-urethral slings and periurethral agents thus helping increase the success of continence procedures, but also explore the aetiology of postoperative complications such as voiding difficulties and tape exposure. Once adequately powered studies establish the validity and accuracy of 3D/4D ultrasound in depicting the exact location of synthetic anti-incontinence slings, subsequent comparison studies between different type of slings (retropubic, transobturator, mini-slings etc) could provide data on the exact mechanism of their action and perhaps explain the variable efficacy rates. Depiction of the exact location of periurethral bulking agents used in the management of persistent or recurrent SUI cases could also explain the highly variable success rates between the different techniques and materials, while prospective
cohort studies could prove valuable in demonstrating the optimal site of injection for maximum effectiveness.

Last but not least important, the use of 2D ultrasound on labour ward should be explored as a means of improving our diagnosis of obstetric anal sphincter complex injuries. The diagnostic accuracy and reliability of two-dimensional translabial ultrasound in detecting 3rd and 4th degree tears in the immediate postpartum period can be tested against 3D/4D translabial ultrasound and digital examination. Should the technique be found valid, the detection rate of occult anal sphincter injuries would improve dramatically, as standard 2D ultrasound machines are readily available in all maternity units in the UK.
REFERENCES


APPENDICES
Prolapse Quality of Life (P-QOL)
Version 4

Name ____________________________

Age ________ years

Today’s date ___/___/____

A PROLAPSE IS A BULGE COMING DOWN THE VAGINA CAUSING DISCOMFORT

PLEASE FILL IN THIS QUESTIONNAIRE EVEN IF YOU FEEL YOU DO NOT HAVE A PROLAPSE

How would you describe your health at present?

Please tick one answer

- Very good □
- Good □
- Fair □
- Poor □
- Very poor □

How much do you think your prolapse problem affects your life?

Please tick one answer

- Not at all □
- A little □
- Moderately □
- A lot □
Please write down if you have any of the following symptoms and mark how much these affect you?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Not applicable</th>
<th>None</th>
<th>A little</th>
<th>Moderately</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowels do not feel completely empty after opening</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Constipation; difficulty in emptying</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Straining to open your bowels</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Vaginal bulge which gets in the way of sex</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Lower backache worsens with vaginal discomfort</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Do you help empty your bowels with your fingers</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

How often do you open your bowels

- More than once a day
- Once a day
- Once every 2 days
- Once every 3 days
- Once a week or more

<table>
<thead>
<tr>
<th>Frequency</th>
<th>○</th>
<th>○</th>
<th>○</th>
<th>○</th>
<th>○</th>
</tr>
</thead>
<tbody>
<tr>
<td>More than once a day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once every 2 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once every 3 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a week or more</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Below are some daily activities that can be affected by your prolapse problem. How much does your prolapse problem affect you?

**We would like you to answer every question.**
Simply tick the circle that applies to you

### ROLE LIMITATIONS

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>To what extent does your prolapse affect your household tasks (e.g. cleaning, shopping etc.)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse affect your job or your normal daily activities outside the home?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### PHYSICAL/SOCIAL LIMITATIONS

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your prolapse affect your physical activities (e.g. going for a walk, run, sport, gym etc.)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse affect your ability to travel?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse limit your social life?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse limit your ability to see / visit friends?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

### PERSONAL RELATIONSHIPS

<table>
<thead>
<tr>
<th></th>
<th>Not applicable</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your prolapse affect your relationship with your partner?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse affect your sex life?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Does your prolapse affect your family life?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
**EMOTIONS**

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your prolapse make you feel depressed?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Does your prolapse make you feel anxious or nervous?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Does your prolapse make you feel bad about yourself?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

**SLEEP / ENERGY**

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>All the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your prolapse affect your sleep?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Do you feel worn out / tired?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

**Do you do any of the following to help your prolapse problem?**
Answer even if you do not feel you have a prolapse problem. If so how much?

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>All the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use tampons / pads / firm knickers to help?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Do you push up the prolapse?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>All the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain or discomfort due to the prolapse?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Does the prolapse prevent you from standing?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

THANK YOU, NOW CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS
Female Sexual Function Index (FSFI) ©

Subject Identifier ___________________________ Date ______________

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner’s sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how often did you feel sexual desire or interest?

☐ Almost always or always
☐ Most times (more than half the time)
☐ Sometimes (about half the time)
☐ A few times (less than half the time)
☐ Almost never or never

2. Over the past 4 weeks, how would you rate your level (degree) of sexual desire or interest?

☐ Very high
☐ High
☐ Moderate
☐ Low
☐ Very low or none at all
Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?

- No sexual activity
- Almost always or always
- Most times (more than half the time)
- Sometimes (about half the time)
- A few times (less than half the time)
- Almost never or never

4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

- No sexual activity
- Very high
- High
- Moderate
- Low
- Very low or none at all

5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?

- No sexual activity
- Very high confidence
- High confidence
- Moderate confidence
- Low confidence
- Very low or no confidence

6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?

- No sexual activity
- Almost always or always
- Most times (more than half the time)
- Sometimes (about half the time)
- A few times (less than half the time)
- Almost never or never
7. Over the past 4 weeks, how often did you become lubricated ("wet") during sexual activity or intercourse?

☐ No sexual activity
☐ Almost always or always
☐ Most times (more than half the time)
☐ Sometimes (about half the time)
☐ A few times (less than half the time)
☐ Almost never or never

8. Over the past 4 weeks, how difficult was it to become lubricated ("wet") during sexual activity or intercourse?

☐ No sexual activity
☐ Extremely difficult or impossible
☐ Very difficult
☐ Difficult
☐ Slightly difficult
☐ Not difficult

9. Over the past 4 weeks, how often did you maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

☐ No sexual activity
☐ Almost always or always
☐ Most times (more than half the time)
☐ Sometimes (about half the time)
☐ A few times (less than half the time)
☐ Almost never or never

10. Over the past 4 weeks, how difficult was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

☐ No sexual activity
☐ Extremely difficult or impossible
☐ Very difficult
☐ Difficult
☐ Slightly difficult
☐ Not difficult
11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how often did you reach orgasm (climax)?

- No sexual activity
- Almost always or always
- Most times (more than half the time)
- Sometimes (about half the time)
- A few times (less than half the time)
- Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how difficult was it for you to reach orgasm (climax)?

- No sexual activity
- Extremely difficult or impossible
- Very difficult
- Difficult
- Slightly difficult
- Not difficult

13. Over the past 4 weeks, how satisfied were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

- No sexual activity
- Very satisfied
- Moderately satisfied
- About equally satisfied and dissatisfied
- Moderately dissatisfied
- Very dissatisfied

14. Over the past 4 weeks, how satisfied have you been with the amount of emotional closeness during sexual activity between you and your partner?

- No sexual activity
- Very satisfied
- Moderately satisfied
- About equally satisfied and dissatisfied
- Moderately dissatisfied
- Very dissatisfied
15. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?

- [ ] Very satisfied
- [ ] Moderately satisfied
- [ ] About equally satisfied and dissatisfied
- [ ] Moderately dissatisfied
- [ ] Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?

- [ ] Very satisfied
- [ ] Moderately satisfied
- [ ] About equally satisfied and dissatisfied
- [ ] Moderately dissatisfied
- [ ] Very dissatisfied

17. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?

- [ ] Did not attempt intercourse
- [ ] Almost always or always
- [ ] Most times (more than half the time)
- [ ] Sometimes (about half the time)
- [ ] A few times (less than half the time)
- [ ] Almost never or never

18. Over the past 4 weeks, how **often** did you experience discomfort or pain following vaginal penetration?

- [ ] Did not attempt intercourse
- [ ] Almost always or always
- [ ] Most times (more than half the time)
- [ ] Sometimes (about half the time)
- [ ] A few times (less than half the time)
- [ ] Almost never or never

19. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?

- [ ] Did not attempt intercourse
- [ ] Very high
- [ ] High
- [ ] Moderate
- [ ] Low
- [ ] Very low or none at all

*Thank you for completing this questionnaire*
### Birmingham Bowel and Urinary Symptoms 22-item Questionnaire

1/ How often do you open your bowels?
- More than 3 times a day  [1]
- 2-3 times a day  [2]
- Once a day  [3]
- Every 1-3 days  [4]
- Less than every 3 days  [5] ▶
- Less than once a week  [6] ▶

2/ Are your motions usually ....
- Watery?  [1]
- Sloppy?  [2]
- Soft and formed?  [3]

3/ Can you hold onto your motions for more than 5 minutes?
- All of the time  [1]
- Most of the time  [2]
- Occasionally  [3] ▶
- Never  [4] ▶

4/ Do you ever have to rush to the toilet to open your bowels?
- Never  [1]
- Occasionally  [2]
- Most of the time  [3] ▶
- All of the time  [4] ▶

5/ Does stool leak before you can get to the toilet?
- Never  [1]
- Occasionally  [2] ▶
- Most of the time  [3] ▶
- All of the time  [4] ▶

6/ Do you leak stool for no obvious reason and without feeling that you want to go to the toilet?
- Never  [1]
- Occasionally  [2] ▶
- Most of the time  [3] ▶
- All of the time  [4] ▶

7/ Do you have to strain to open your bowels?
- Never  [1]
- Occasionally  [2]
- Most of the time  [3] ▶
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>14/ Have you consulted a doctor in the last six months about constipation?</td>
<td>Yes [1] ➤ No [2]</td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>16/ During the day, how many times do you urinate, on average?</td>
<td>1 to 6 times [1]</td>
</tr>
<tr>
<td></td>
<td>7 to 9 times [2]</td>
</tr>
<tr>
<td></td>
<td>10 to 12 times [3]</td>
</tr>
<tr>
<td></td>
<td>13 times or more [4]</td>
</tr>
<tr>
<td>17/ During the night, how many times do you have to get up to urinate,</td>
<td>Never [1]</td>
</tr>
<tr>
<td>on average?</td>
<td>1 time [2]</td>
</tr>
<tr>
<td></td>
<td>2 times [3]</td>
</tr>
<tr>
<td></td>
<td>3 times or more [4]</td>
</tr>
<tr>
<td>18/ Do you have to rush to the toilet to urinate?</td>
<td>Never [1]</td>
</tr>
<tr>
<td></td>
<td>Occasionally [2]</td>
</tr>
<tr>
<td></td>
<td>Most of the time [3]</td>
</tr>
<tr>
<td></td>
<td>All of the time [4]</td>
</tr>
<tr>
<td>19/ Do you have difficulty completely emptying your bladder?</td>
<td>Never [1]</td>
</tr>
<tr>
<td></td>
<td>Occasionally [2]</td>
</tr>
<tr>
<td></td>
<td>Most of the time [3]</td>
</tr>
<tr>
<td></td>
<td>All of the time [4]</td>
</tr>
<tr>
<td>20/ Does urine leak before you can get to the toilet?</td>
<td>Never [1]</td>
</tr>
<tr>
<td></td>
<td>Occasionally [2]</td>
</tr>
<tr>
<td></td>
<td>Most of the time [3]</td>
</tr>
<tr>
<td></td>
<td>All of the time [4]</td>
</tr>
<tr>
<td>21/ Does urine leak when you are active, exert yourself, cough or</td>
<td>Never [1]</td>
</tr>
<tr>
<td>sneeze?</td>
<td>Occasionally [2]</td>
</tr>
<tr>
<td></td>
<td>Most of the time [3]</td>
</tr>
<tr>
<td></td>
<td>All of the time [4]</td>
</tr>
<tr>
<td>22/ Does urine leak for no obvious reason and without feeling that you</td>
<td>Never [1]</td>
</tr>
<tr>
<td>want to go to the toilet?</td>
<td>Occasionally [2]</td>
</tr>
<tr>
<td></td>
<td>Most of the time [3]</td>
</tr>
<tr>
<td></td>
<td>All of the time [4]</td>
</tr>
</tbody>
</table>
CONSORT 2010 Flow Diagram

1. Enrollment
   - Assessed for eligibility (n= )
     - Excluded (n= )
       - Not meeting inclusion criteria (n= )
       - Declined to participate (n= )
       - Other reasons (n= )

2. Randomized (n= )

3. Allocation
   - Allocated to intervention (n= )
     - Received allocated intervention (n= )
     - Did not receive allocated intervention (give reasons) (n= )
   - Allocated to intervention (n= )
     - Received allocated intervention (n= )
     - Did not receive allocated intervention (give reasons) (n= )

4. Follow-Up
   - Lost to follow-up (give reasons) (n= )
   - Discontinued intervention (give reasons) (n= )
   - Lost to follow-up (give reasons) (n= )
   - Discontinued intervention (give reasons) (n= )

5. Analysis
   - Analysed (n= )
     - Excluded from analysis (give reasons) (n= )
   - Analysed (n= )
     - Excluded from analysis (give reasons) (n= )