UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE, HEALTH & LIFE SCIENCES

School of Health Sciences

Dynamic Evaluation of Female Pelvic Floor Muscle Function Using 2D Ultrasound and Image Processing Methods

by

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MCSP Grad Dip Phys

Thesis for the degree of Doctor of Philosophy

Correction Sheet

ABSTRACT

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES

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Doctor of Philosophy

DYNAMIC EVALUATION OF FEMALE PELVIC FLOOR MUSCLE FUNCTION USING 2D ULTRASOUND AND IMAGE PROCESSING METHODS.

by Ruth Cerian Lovegrove Jones MCSP

The aim of this study was to define new quantitative parameters of dynamic Pelvic Floor Muscle (PFM) function using 2D transperineal (TP) ultrasound imaging combined with image processing methods (IPM).

Ultrasound and digital vaginal data were obtained from a volunteer convenience sample of 23 continent and 9 Stress Urinary Incontinent (SUI) women recruited from the San Francisco Bay Area community, California, U.S.A.

Two methods of IPM were used; speckle tracking for measuring displacement of the ano-rectal angle (ARA) and symphysis pubis (SP); and segmentation IPM for measuring displacement of the urethra. Good to excellent inter and intra observer reliability was established for processing the ultrasound images on stored audio-visual imaging files (AVI). Intraclass correlation coefficient (ICC) values: 0.61 to 0.99; 95% confidence intervals (CI) 0.08→0.84 to 0.97→0.99; standard error of measurement (SEM) 0.01to 0.25 cm. There was good agreement between measures on Bland and Altman analysis: mean difference 0.06 to -0.21 cm; 95% CI 0.02→0.45cm to -0.01→0.20cm. Validity of the IPM was confirmed with digital palpation, and furthermore indicated good sensitivity and specificity. Technical and methodological limitations of the IPM, and suggestions for future studies were discussed.

Several research questions were addressed using TP ultrasound combined with IPM that enabled the dynamic evaluation of pelvic floor (PF) displacement throughout an entire manoeuvre, rather than limiting the quantification from static images at rest to the end of the manoeuvre. In this way, IPM determined unique quantitative data regarding the automatic displacement, velocity and acceleration of the ARA and urethra during a cough, Valsalva, voluntary PFM contraction, The Knack and a Transversus Abdominis contraction. During automatic events that raised intra-abdominal pressure (IAP), normal PFM function produced timely compression of the PF and additional external support to the urethra, reducing the displacement, velocity, and acceleration. In women with SUI, who have weaker urethral attachments, this shortening contraction did not occur; consequently, the urethra of women with SUI moved further and faster for a longer duration.

Caution regarding the generalisability of this study is warranted due to the small number of women in the SUI group and the significant difference in parity between groups. However this non-invasive physiological measurement tool demonstrated a new way of assessing the PFM. It is envisaged that this study will provide the foundation for future studies with larger parity matched populations and eventually improve the rehabilitation of women with SUI and other PF disorders.

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Declaration of Authorship

I Ruth Cerian Lovegrove Jones declare that the thesis entitled "Dynamic Evaluation of Female Pelvic Floor Muscle Function Using 2D Ultrasound and Image Processing Methods" and the work presented in it are my own. I confirm that:

- this work was done wholly or mainly while in candidature for a research degree at this University;
- no part of this thesis has been previously submitted for a degree or any other qualification at this University or any other institution;
- Where I have quoted from the work of others, the source of this is always given. With the exception of such quotations, this thesis is entirely my own work;
- I have acknowledged all main sources of help;
- Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- parts of this work have been published before submission as:

Peng Q, Jones RC, Constantinou C (2006). 2D Ultrasound Image Processing in Identifying Responses of Urogenital Structures to Pelvic Floor Muscle Contractions. Annals Biomedical Engineering 34(3); 477-93

Peng Q, Jones R, Shishedo K & Constantinou C (2007). Ultrasound Evaluation of Dynamic Responses of Female Pelvic Floor Muscles. Ultrasound in Medicine and Biology.

Peng Q, Jones R, Shishido K, Omata S, & Constantinou CE (2007). Spatial distribution of vaginal closure pressures of continent and stress urinary incontinent women. Physiological Measurement 28, 1429-1450.

Rahmanian S, Jones R, Peng Q, & Constantinou CE (2008). Visualization of biomechanical properties of female pelvic floor function using video motion tracking of ultrasound imaging. Studies in Health Technology & Informatics 132, 390-395.

Shishido K, Peng Q, Jones R, Omata S, & Constantinou CE (2008). Influence of pelvic floor muscle contraction on the profile of vaginal closure pressure in continent and stress urinary incontinent women. Journal of Urology 179, 1917-1922.

Lovegrove Jones RC, Peng Q, Stokes M, Humphrey VF, Payne C, & Constantinou CE Mechanisms of Pelvic Floor Muscle Function and the Effect on the Urethra during a Cough. European Urology In Press, Corrected Proof.

Signed Date

Acknowledgements

To Dr Qiyu Peng, PhD for assistance throughout the research study, particularly developing the image processing methods and mathematical algorithms used in the ultrasound analysis. Without him, this project would have been almost impossible.

To Dr Chris Constantinou, PhD (Supervisor) who not only provided the opportunity to work with such a great team at Stanford, but also taught me to use my ears in proportion to my mouth. Thank-you also, for taking the time to understand how I learn…registration ala hand gestures.

To Professor Maria Stokes, PhD (Primary Supervisor) whose faith in my ability assisted my own self belief. You gave some well needed structure to the mishmash of ideas and the pages of this thesis owe much to your scientific rigour. Thank you.

To Professor Victor Humphries, PhD (Supervisor) for having such an empowering way of explaining the fundamentals of physics and wave form analysis; and keeping me on the straight and narrow path of good science.

Dr Christopher Pagne, Professor Inder Perkash, Vicky Wolf and Tina Alley for assistance in the experimental aspects of the study.

To all the women who participated in this intimate study.

To Maeve Whelan, Specialist Womens Health physiotherapist who provided the initial inspiration, the roof top Macy Gray and of course, the Limoncello. If that was not enough, she freely contributed her expertise, her drawings illustrating some of the concepts, and most valuably, her time when I most needed it and she didn't have it. Thanks, I owe you.

To all the womens health physiotherapists who came before me, making my journey so much easier, particularly Jo Laycock, OBE PhD, FCSP and Jeanette Haslam MPhil, MCSP who have been a constant source of inspiration and guidance.

To my new, yet lifelong friends in California, especially Drew, Ross, Dipita and Beata and the whole yoga community at YIY. You know what you did. I could not have achieved this without you.

To my Mum and Allan, for contributing all they have, with love, grace and a warm heart.

To Cerryg and Catrin, for reminding me that you'd still love me even if I failed ☺

To my husband Steve and daughter Hannah, for being there, loving and supporting me. Without you, life means nothing. I promise not to do anything like this again. If I waver, you have my permission to lock me away until I see sense.

Nameste.

List of Abbreviations

ARA....................Ano-rectal Angle
ATFP....................Arcus Tendineus Fascia Pelvis
ATLA....................Arcus Tendineus Levator Ani
AVI....................Audio Visual Images
BN....................Bladder Neck
CI....................Confidence Intervals
CNS....................Central Nervous System
CP....................Christopher Payne
EMG....................Electromyography
FOB....................Flock of Birds
IAP....................Intra-abdominal Pressure
ICC....................Intra-class Correlation Coefficient
ICS....................International Continence Society
IIQ....................Incontinence Impact Questionnaire
IPM....................Image Processing Methods
Kw....................Weighted Kappa
LUT....................Lower Urinary Tract
MRI....................Magnetic Resonance Imaging
PF....................Pelvic Floor
PFCAG....................Pelvic Floor Clinical Assessment Group
PFM....................Pelvic Floor Muscles
POP....................Pelvic Organ Prolapse
QP....................Qiyu Peng
RCT....................Randomised Controlled Trial
RLJ....................Ruth Lovegrove Jones
RUSI....................Rehabilitative Ultrasound Imaging
TA....................Transabdominal
TL....................Translabial
TP....................Transperineal
TR....................Transrectal
TV....................Transvaginal
TrA....................Transversus Abdominis

SD .... Standard Deviation
SE .... Standard Error
SEM .... Standard Error of Measurement
SP .... Symphysis Pubis
SUI .... Stress Urinary Incontinence
TrA .... Transversus Abdominis
UDI .... Urogenital Distress Inventory
USI .... Ultrasound Imaging
UI .... Urinary Incontinence
UK .... United Kingdom
UVJ .... Urethro-Vesical Junction
VPP .... Vagina Pressure Profile
2D .... 2 Dimensional
3D .... 3 Dimensional

1 Introduction

This chapter briefly discusses the rationale behind the current research which aims to define new quantitative parameters of pelvic floor muscle (PFM) function using 2D perineal ultrasound and image processing methods (IPM). It familiarises the reader to the anatomy of the pelvic floor (PF), defines urinary incontinence and presents a clinically relevant overview of PFM functional anatomy, specifically related to Stress Urinary Incontinence (SUI). Existing instrumentation to measure the PFM are discussed and the basic principles, modes and applications of ultrasound imaging presented. The outline and structure of the rest of the Thesis are then described.

1.1 Context of the investigation: the dynamic function of female pelvic floor muscles:

There is increasing evidence that the PFM perform multiple functions such as: continence and pelvic organ support (DeLancey, 1990;Howard *et al.*, 2000); sexual function (Baytur *et al.*, 2005); respiration (Hodges *et al.*, 2007) spinal stability and containment of intra-abdominal pressure (IAP) (Hemborg *et al.*, 1985;Pool-Goudzwaard *et al.*, 2004;Smith *et al.*, 2008). The physiological mechanisms by which they perform these roles are not clearly understood, predominately due to a lack of suitable instrumentation. The female PF remains, particularly from a biomechanical perspective, an understudied region of the body (Ashton-Miller & DeLancey, 2007). PF dysfunction for certain, encompasses both urinary and faecal incontinence, pelvic organ prolapse (POP), and pelvic pain (Martins *et al.*, 2007). It is a significant problem for women and has been termed the hidden epidemic (DeLancey, 2005) with estimates in the USA indicating that that between 21% to 26% of American women have at least one PF disorder, with the greatest percentage experiencing urinary incontinence(UI) (Nygaard *et al.*, 2008). PF dysfunction affects between 300,000 and 400,000 American women so severely that they require surgery, and 30% of those will require re-operations (Olsen *et al.*, 1997;Boyles *et al.*, 2003). Similar prevalence data of PF dysfunction is currently unavailable in the UK.

To date, PFM dysfunction in relation to SUI has been the pathology more extensively studied, particularly from a conservative rehabilitation perspective (Dumoulin & Hay-Smith, 2008). Several randomised controlled trials have demonstrated that PFM strength training in women with SUI is more effective than untreated controls or other treatment modalities, with varying cure rates between 44% and 67% (Miller *et al.*, 1998;Henalla *et al.*, 1988;Morkved *et al.*, 2002;Dumoulin *et al.*, 2004b) . Yet although strength training is effective, strength of PFM contraction does not always correlate with continence state (Kessler & Constantinou, 1986;Theofrastous *et al.*, 2002;Morin *et al.*, 2004a). It is unclear why rehabilitation is effective in some women and not in others as little research has focused upon the mechanisms of therapeutic change to help identify the critical components of training. Although there are exceptions, (Miller *et al.*, 2001;Dumoulin *et al.*, 2004b;Miller *et al.*, 2008), most conservative treatment and assessment options remain focused upon strength training and they have rarely, if ever, considered other properties of PFM function, such as timing and direction of contraction, endurance, the ability of the PFM to relax, over- activity of the PFM, pelvic organ support and co-ordination with muscles of the abdominal-pelvic cylinder. Given the multi-purpose role of the PFM, the motor control challenge of the PFM will be immense and the efficiency of the PFMs would not only rely upon the anatomical integrity of the PF, but would depend on the central nervous system (CNS) response to satisfy hierarchical demands of function. The CNS must interpret the afferent input and generate a coordinated response so that the muscles' activity occurs at the right time, with the appropriate level of force.

A combination of neuropathic changes, muscle, fascial or connective tissue damage is most likely responsible for the development of PF disorders yet the precise mechanisms remain controversial (Shafik *et al.*, 2005;Ashton-Miller & DeLancey, 2007;Petros, 2007;Smith *et al.*, 2007b). It would seem logical that knowing the exact nature of each woman's condition and directing treatment to the specific dysfunction, would improve treatment success. As it is likely that the PFM are also affected in conditions other than SUI, it was hoped that this feasibility study could provide a novel way of measuring PFM function. This would then contribute to the existing knowledge base of PFM function and would provide support for the foundations of future PFM research.

1.2 Gross anatomy of the pelvis

The bony pelvis consists of the sacrum, coccyx and two innominates; which are joined by strong ligamentous attachments posteriorly at the sacro-iliac joints and anteriorly at the symphysis pubis (SP), and is closed inferiorly by the PF. Superiorly, the respiratory diaphragm forms the top of the lumbo-pelvic cylinder, transversus abdominis (TrA) the sides and the spinal column runs through the middle, supported posteriorly by segmental attachments of lumbar multifidus, anteriorly by segmental attachments of psoas and the abdominal muscles (Figure 1.1)

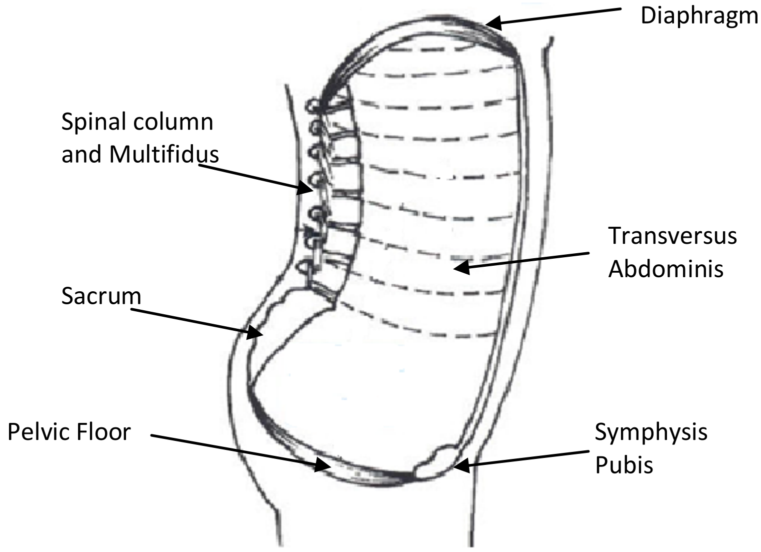

Figure 1.1: Schematic of the lumbo-pelvic cylinder in which the respiratory diaphragm forms its top, transversus abdominis the sides and pelvic floor the bottom.

The female PF is an intricate, complicated structure, and by virtue of its anatomical position, makes it a challenging area to study. The support mechanisms of the PF are responsible for the maintenance of continence and prevention of pelvic organ prolapse (POP) during rises of intra-abdominal pressure (IAP) (Ashton-Miller & DeLancey, 2007), so functionally it not only has to allow the passage of urine and faeces at the appropriate time, it must also prevent incontinence. The PF is essential for sexual activity, conception, fertility and vaginal delivery (Herschorn, 2004;DeLancey, 2005) and more recently the PF has been implicated in contributing to spinal stability and respiration (Hodges *et al.*, 2007). It is thought that the PFM contribute to spinal stability by stiffening the sacro-iliac joints (Pool-Goudzwaard *et al.*, 2004) and indirectly the lumbar spine through contributing to rises in IAP (Hodges & Gandevia, 2000).

1.3 Female pelvic viscera

Bladder and urethra: The lower urinary tract (LUT) can be divided into the bladder (or detrusor) and urethra, with the junction of these two continuous structures termed the bladder (vesical) neck (BN) or urethra-vesical junction (UVJ) (Figure 1.2). The bladder is attached by ligaments and fascia to the side walls of the pelvis and pubic bones.

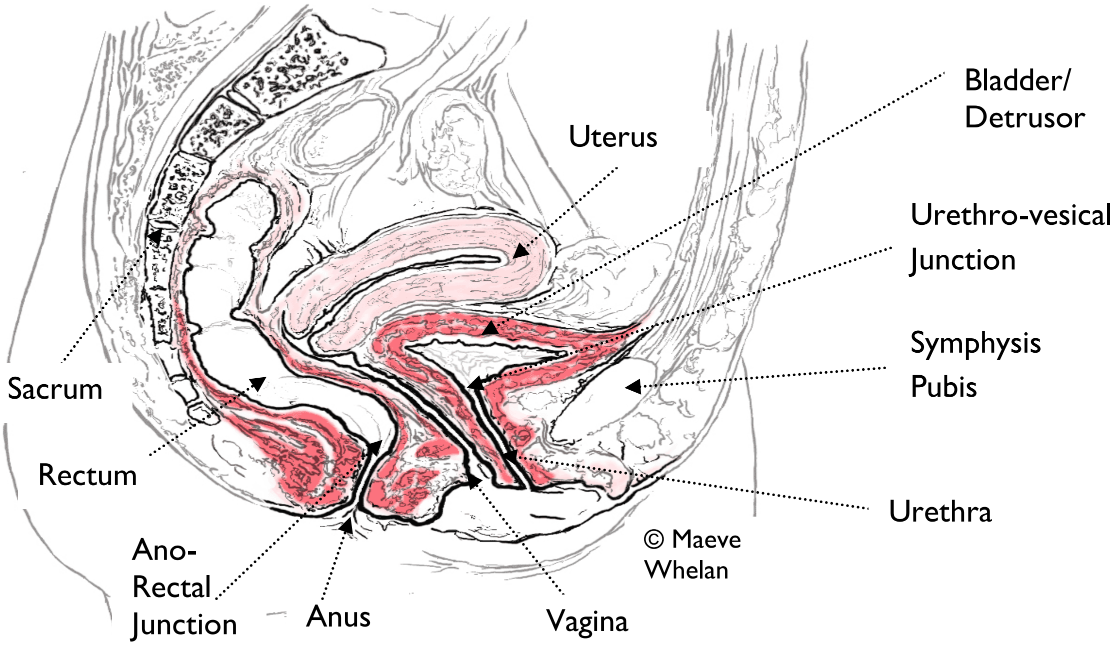

Figure 1.2: Sagittal cross section of Female Pelvis indicating main pelvic viscera and bony landmarks. Pictures copyright and courtesy of Maeve Whelan, Specialist Womens Health Physiotherapist, Dublin, Ireland.

The urethra is a highly vascular multilayered tube approximately 0.6cm in diameter and 3-4 cm in length (Strohbehn *et al.*, 1996). The outer layer of the urethra is formed by the muscle of the striated urogenital sphincter whose fibres lie predominately in a circular orientation in the upper two-thirds of the urethra. The striated urogenital sphincter muscle region of the ventral urethral wall has three component parts: the sphincter urethrae; the compressor urethrae and the urethrovaginal sphincter (Figure 1.3).

Figure 1.3: Lateral view of urethral and PF muscular anatomy. BC, bulbocavernosus; CU, compressor urethrae; D, detrusor; LA, levator ani; US, urethral sphincter; UVS, urethrovaginal sphincter (With permission DeLancey 2004).

The smooth muscle of the urethra is present in the upper four fifths of the urethra, lies inside the striated urogenital sphincter and is contiguous with the bladder. The orientations of the inner fibres are longitudinal whilst the outer layers are circular (Strohbehn *et al.*, 1996) (Figure 1.4).

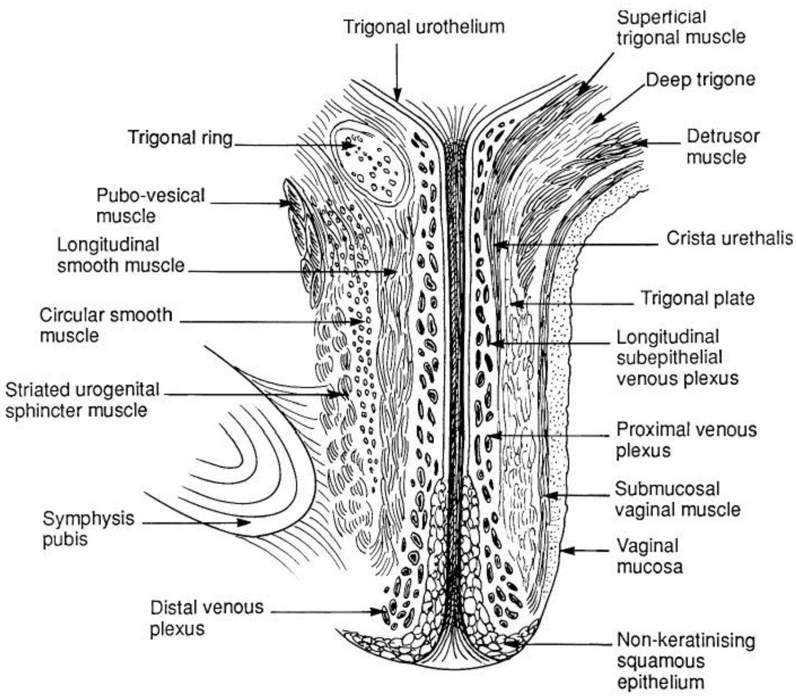

Figure 1.4: Anatomy of the urethra shown in longitudinal section. Reprinted with permission from (Strohbehn *et al.*, 1996)

In the female urethra, closure pressure is known to be developed principally by contraction of the smooth and striated muscle (Perucchini *et al.*, 2002b). All elements of the striated urogenital sphincter muscle are found in the ventral urethral wall, whereas the dorsal wall contains only the sphincter urethrae because the urethrovaginal sphincter and the compressor urethrae diverge from the urethral wall to pass laterally toward the ischiopubic ramus and the vaginal wall (Oelrich, 1983).

Vagina and Uterus: The vagina is a fibro-muscular structure, resting on the rectum, lying posterior to the urethrovesical system (Figure 1.2). It is attached laterally to the vaginal walls by combination of fascia and connective tissue containing smooth muscle, elastic fibres nerves and vessels. The distal third of the vagina is fused with the urethra anteriorly, the perineal body posteriorly, and the perineal membrane and PFM laterally. (Peschers & DeLancey, 2008). The uterus lies behind and above the bladder, in front of the rectum. The neck of the uterus is the cervix which is directly attached to the vaginal wall.

Rectum and Anal Canal: Directly behind the posterior vaginal wall of the vagina is the anterior wall of the rectum (Figure 1.2). The rectum is the lowest part of the gastrointestinal tract and is continuous above with the sigmoid colon and below with the anal canal. The rectum is composed of a circular and longitudinal layer of smooth muscle. At its distal end, the circular layer thickens to form the internal anal sphincter. The **external anal sphincter** is placed outside the internal sphincter, between which are fused longitudinal fibres of the intestinal wall and PFM muscles (Figure 1.4, 1.8, 1.9) (Peschers *et al.*, 1997a).

1.4 Pelvic floor muscles (PFM)

The PFM are the collective name for the muscles of the PF; unfortunately throughout the literature, there still remains lack of consensus regarding their description and terminology. A recent review of the literature revealed over 16 different overlapping terms for different parts of the muscle, yet the anatomy was found to be very consistent amongst different studies (Kearney *et al.*, 2004). Kearney et al concluded that confusion could be limited by standardising terminology based upon origin and insertion points of the muscle. Therefore, for the purposes of this Thesis, wherever possible, nomenclature is based upon origin-insertion points.

1.4.1 The deep PFM: levator ani muscle

The levator ani is covered by connective tissue on its superior and inferior surfaces, and with the corresponding muscle from the opposite side, it is often referred to as the pelvic diaphragm. It provides the main muscular support for the pelvic viscera and is divided into two parts: the **pubovisceral** muscle and the **iliococcygeal** muscle. **The Pubovisceral muscle** is a thick U shaped muscle which arises from the pubic bones on either side of the midline and a band of fascia, the arcus tendineus levator ani (ATLA) laterally (Figure 1.5). It passes behind the rectum forming a sling-like arrangement, attaching to the walls of the vagina, perineal body and anal sphincter. The pubovisceral muscle can then be divided into three main components based upon the anatomical attachments; puborectalis, pubovaginalis and pubococcygeus (Figure 1.6). The puborectalis portion passes beside the vagina with some attachment to the lateral vaginal walls. Some other fibres insert into the rectum, and others pass behind the anorectal junction. The fibres of the pubovaginalis pass between the vagina and pubis, connecting to the fascia that supports the urethra. Pubococcygeus only comprises of a small proportion of the levator complex, although clinicians have often referred to the entire pubovisceral muscle as pubococcygeus. Its fibres pass from the pubic bones to the coccyx, with some extending behind the rectum and to the anal canal. **The iliococcygeal muscle** is attached from one side wall of the pelvis to the other via fascia, and forms a horizontal shelf on which the pelvic organs rest.

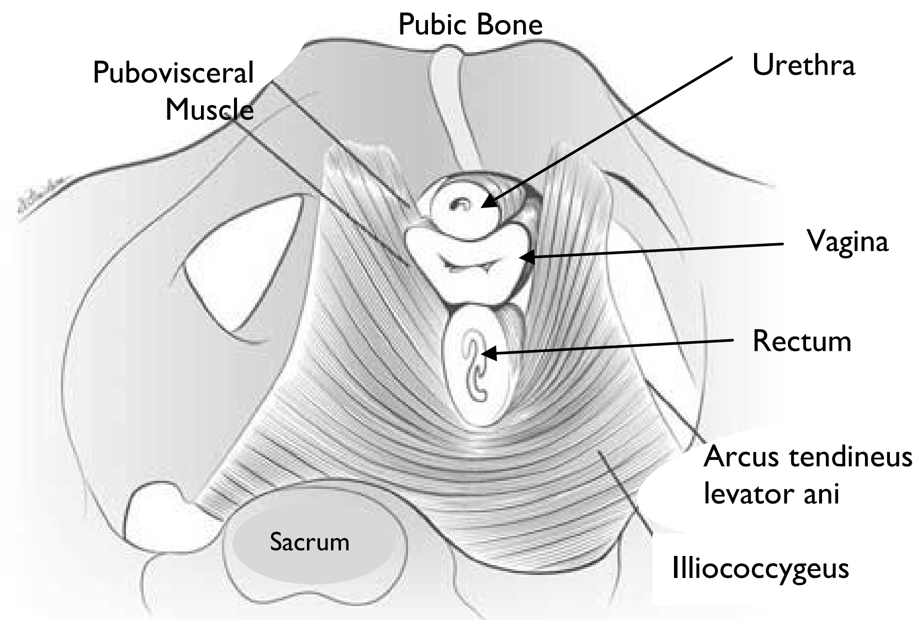

Figure 1.5: Levator ani muscle seen from above (Adapted from Kearney et al. 2004 with permission of Elsevier North Holland, New York, © DeLancey 2003)

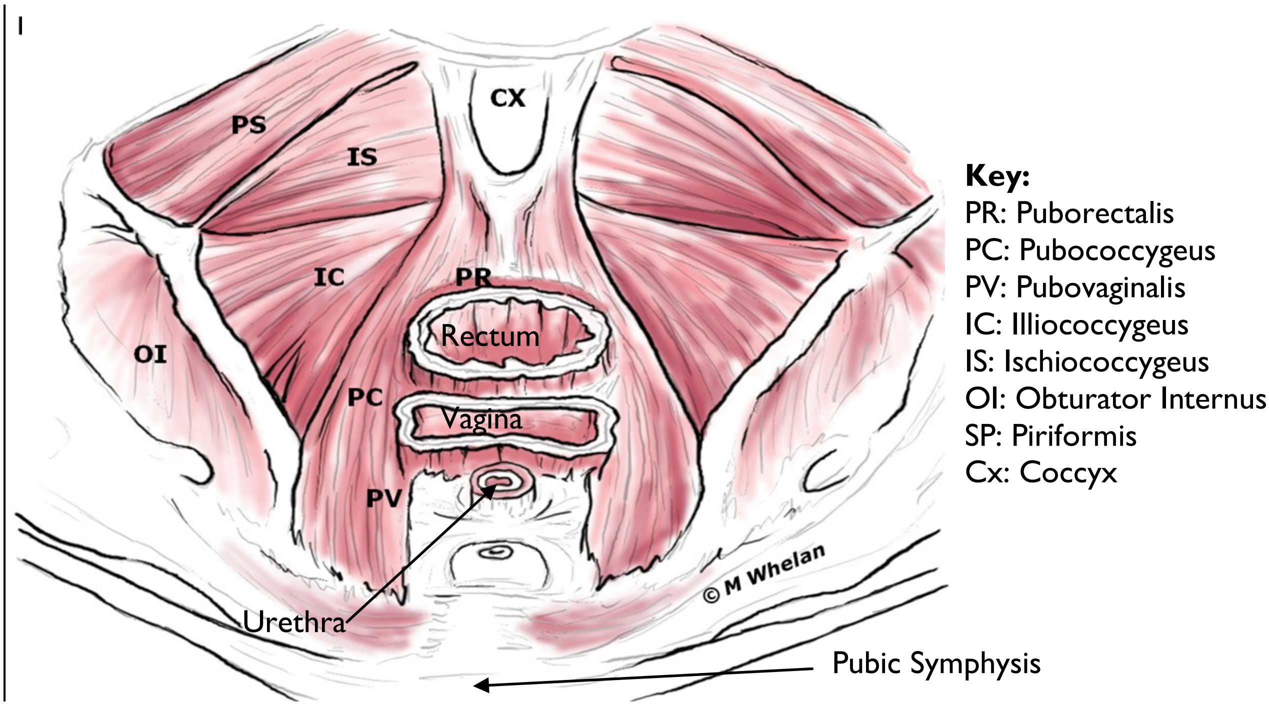

Figure 1.6: Schematic of the Pelvic Floor illustrating the orientation of the horizontal clock, coccyx at 12 o'clock, and perineal body at 6 o'clock. Pictures courtesy of Maeve Whelan, Specialist Womens Health Physiotherapist, Dublin, Ireland.

1.4.2 The superficial PFM and perineal body

Along with the connective tissue membrane surrounding them, the superficial PFM is often called the perineal membrane or urogenital diaphragm (Figure 1.7, 1.8). The perineal membrane lies level with the hymenal ring and attaches the urethra, vagina and perineal body to the ischio-pubic rami. The perineal body is a fibro-muscular structure containing smooth muscle, elastic fibres and nerve endings in the middle of the perineum, between the anus and vagina (Figure 1.7, 1.8).

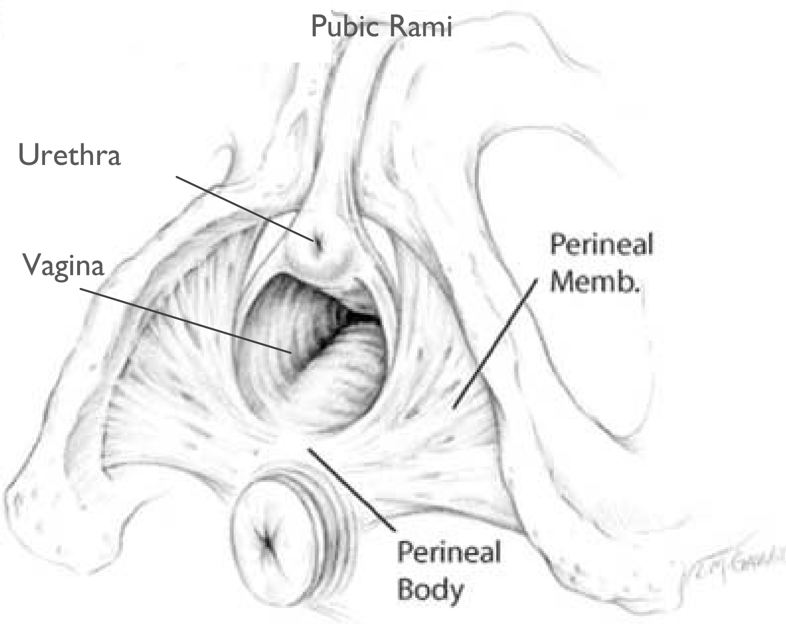

Figure 1.7: Perineal membrane spans the arch between the ischio-pubic rami with each side attached to the other through their connection in the perineal body. (With permission DeLancey 1999)

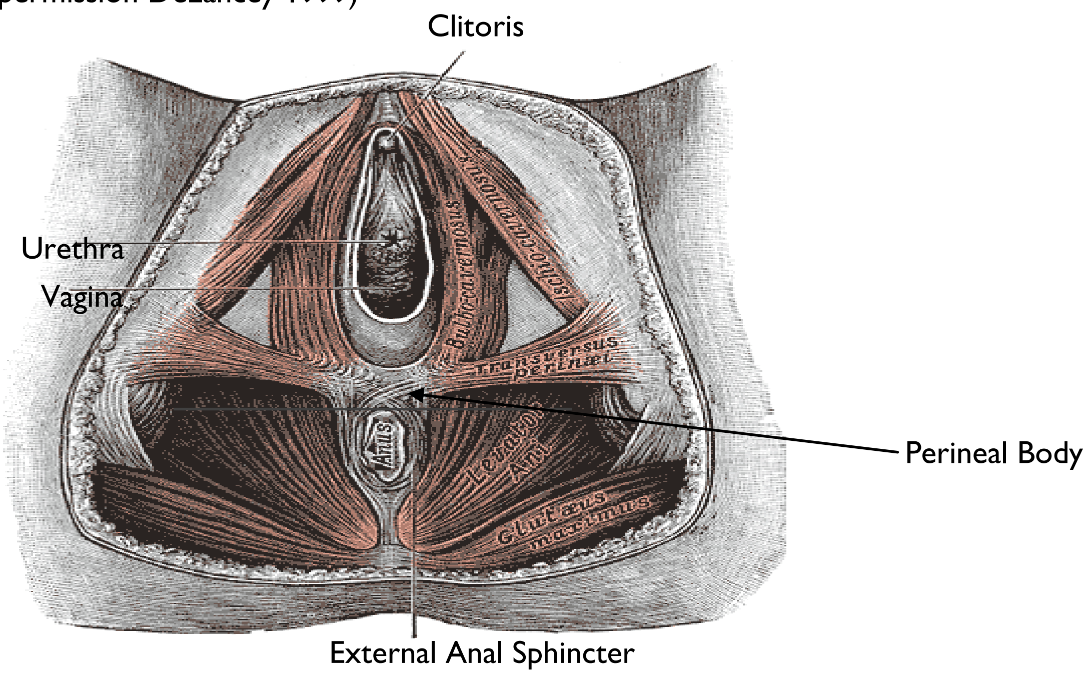

Figure 1.8: Superficial muscles of the pelvic floor from Gray's Anatomy of the Human Body .

Fibres of the rectum and anal sphincter, superficial PFM and levator ani also extend into the perineal body (Herschorn, 2004). There is no consensus over the anatomical configuration of these muscles and fascia (Oelrich, 1983;DeLancey, 1999) yet the striated muscle fibres are generally thought of as the transverse perinei superficialis, urogenital sphincters (compressor urethrae, urethrovaginal) and external anal sphincters (Figures 1.4, 1.8, 1.9). The bulbocavernous and ischiocavernosus are the most superficial layer of the PF and have a mainly sexual function (Peschers & DeLancey, 2008).

1.4.3 Endopelvic fascia

The endopelvic fascia is the collective name given to the connective tissue that attaches the bladder, urethra, vagina and uterus to the pelvic walls (Figure 1.9). The pelvic sidewall attachment of the endopelvic fascia is called the arcus tendineus fascia pelvis (ATFP) which is attached to the pubic bone ventrally and to the ischial spine dorsally (Ashton-Miller *et al.*, 2001).

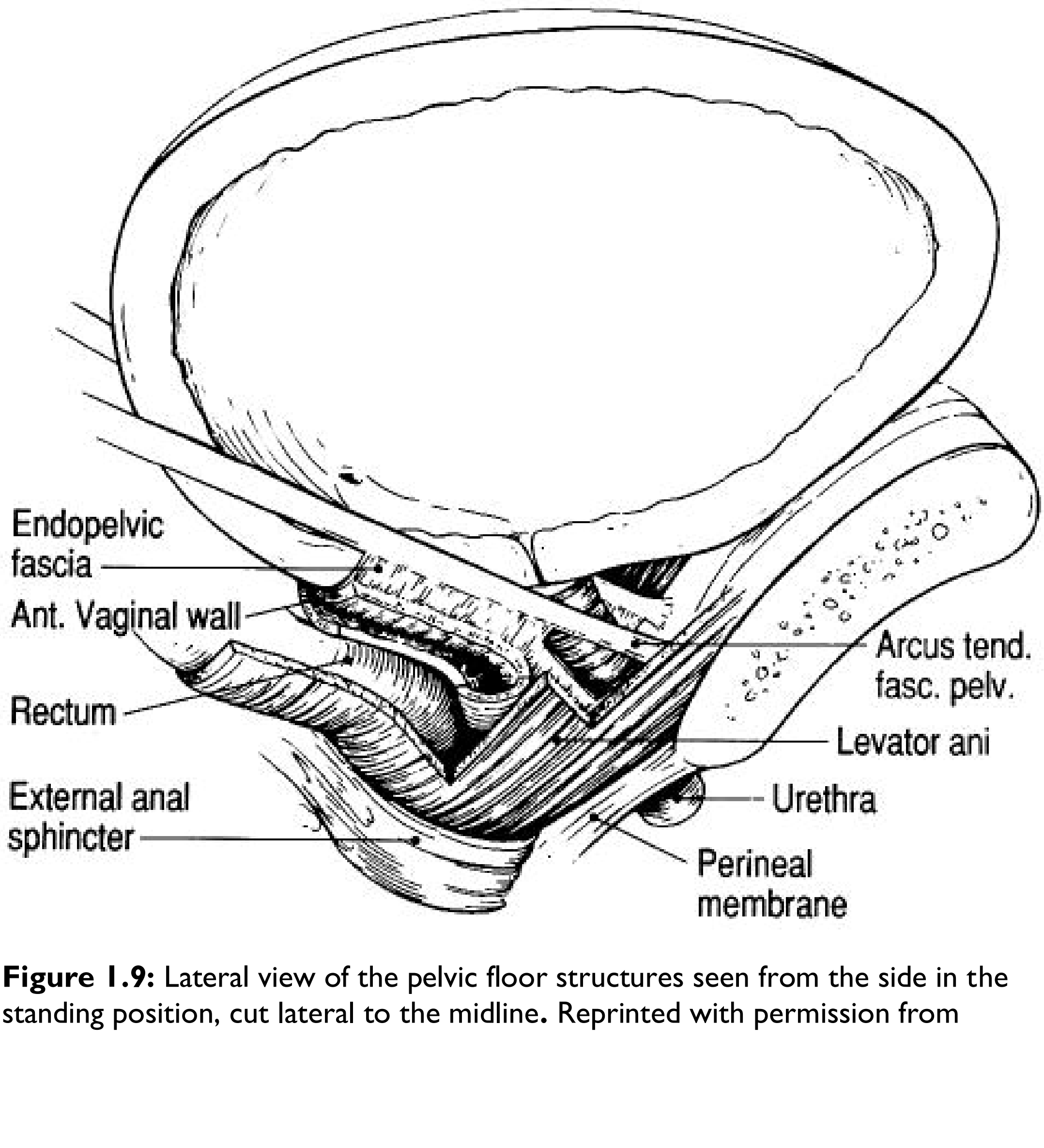

Figure 1.9: Lateral view of the pelvic floor structures seen from the side in the standing position, cut lateral to the midline**.** Reprinted with permission from

The ATFP is well defined anteriorly, and lies approximately 3cm below the levator ani muscle. Posteriorly it is more like a broad sheet of fascia, blending with the endopelvic fascia, and merges with the levator ani. Near the spine, the ATFP fuses with the arcus tendineus levator ani (ATLA) which is the band of fascia that the levator ani arises from (Figure 1.5).

1.5 The innervation of the pelvic organs and PFM

Neural control of pelvic organs is affected by a unique coordination of somatic and autonomic motor nervous systems; sensory information and feedback is supplied by both visceral and somatic sensory fibre systems (Enck & Vodusek, 2006). The levator ani muscles have constant myoelectric activity and are composed of smooth and striated muscle fibres (Shafik *et al.*, 2002), approximately two-thirds of which are type I (Gosling *et al.*, 1981) reflecting their predominately support function (Shafik *et al.*, 2003). Although there are differences of opinion regarding the exact innervation of the PFM, there is consensus that the nerve supply is from the pudendal nerve with direct branches from the sacral nerves S3-S4 (Shafik, 2000;Guaderrama *et al.*, 2005a;Grigorescu *et al.*, 2008). It is thought that the PFM predominately contract or relax en masse (Shafik, 1998). Yet due to the separate, though identical innervation of each individual muscle, there may also exist the capacity for voluntary selective activity by which an individual muscle might behave independently from the others (Shafik, 1998;Kenton & Brubaker, 2002).

1.6 Urinary continence

The definitions of urinary incontinence by the International Continence Society (ICS) have been written to be compatible with the WHO publication ICIDH-2 (International Classification of Functioning, Disability and Health) published in 2001 and ICD10, the International Classification of Diseases http://www.who.int/icidh.

Urinary incontinence (UI) is defined as "the complaint of any involuntary leakage of urine" (Abrams *et al.*, 2002). There are many forms of UI, however the three most common forms are:

- SUI: "the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing";
- Urgency urinary incontinence: "the complaint of involuntary leakage accompanied by or immediately proceeded by urgency" where urgency is defined as "the

complaint of a sudden compelling desire to pass urine which is difficult to defer";

- Mixed urinary incontinence: "the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing".

1.6.1 Prevalence and aetiology of urinary incontinence in women

Although the prevalence of UI has been shown to vary widely, it is a common condition in women, ranging from 8.5% to 38% depending upon age, parity and definition (Nitti, 2001). In adult women, several European studies have provided estimations mostly between 20% and 50% (Gerrits *et al.*, 2008). A longitudinal study of 4,214 parous women carried out over 6 years in the United Kingdom (UK) and New Zealand suggested that the incidence of persistent UI was 24%, 6 years after birth (MacArthur *et al.*, 2006). Similar rates are cited in Italian (Siracusano *et al.*, 2003), Norwegian (Hannestad *et al.*, 2000) and Austrian women, 66% of which stating that their quality of life was impaired because of their incontinence (Temml *et al.*, 2000).

Prevalence rates could be even higher as it is thought that many women do not seek medical advice, citing a number of reasons such as embarrassment, hope of gradual improvement, fear of surgery, the belief that incontinence is a normal condition of childbirth or ageing, or conversely that they considered their symptoms to be slight and not worth reporting (Ashworth & Hagan, 1993;Grimby *et al.*, 1993;Shaw *et al.*, 2006).

1.7 Functional anatomy of SUI

The causes of UI are multi-factorial and not completely understood, however identifiable risk factors include pregnancy, childbirth, menopause, obesity, familial history, connective tissue factors, cognitive impairment and increasing age (Allen *et al.*, 1990;Snooks *et al.*, 1990;Bump & Norton, 1998;Kuh *et al.*, 1999;Groutz *et al.*, 1999;Perucchini *et al.*, 2002b;Rortveit *et al.*, 2003;Hannestad *et al.*, 2004;Groutz *et al.*, 2007). In the literature, there remain differences of opinion regarding the anatomy, innervation and physiology of the PFM, urethral sphincters and urethra, particularly in relation to the underlying pathophysiology of urinary incontinence (Shafik *et al.*, 2005;Petros, 2007;Ashton-Miller & DeLancey, 2007). Although many researchers have questioned the validity and reproducibility of the theoretical mechanisms of SUI, four theories have dominated the literature based on the physiology of continence and the observations of the researcher current at that time (Daneshgari & Moore, 2006).

Enhorning based his theory of SUI on an alteration in urethral angles and studied the pressures of the urethra and the bladder in continent and incontinent women (Enhorning, 1961). He concluded that, for urethral competence, the urethra should be located above the pelvic floor, so that the pressure transmitted to the bladder was equally transmitted to the urethra, causing a compensatory increase in closure pressure.

McGuire suggested that SUI resulted from more than an anatomical change in urethral position and demonstrated the importance of the resting urethral pressure or urethral smooth muscle function in maintaining continence (McGuire, 1978;McGuire, 1981). He proposed that intrinsic urethral deficiency, anatomical deficits or a combination of both could be responsible for SUI (McGuire *et al.*, 1993).

The "integral theory" (Petros & Ulmsten, 1990) suggested that SUI was due to an anatomical defect which produced laxity in the vagina or its supporting ligaments. They proposed that laxity of the pubourethral ligament and anterior vaginal wall would result in bladder neck hypermobility and the dispersion of urethral closure pressures created by both the PFM and intra-abdominal pressure during stress events.

Although there are merits and questions regarding all theoretical mechanisms of SUI, for the purposes of this Thesis, the functional anatomical section as it relates to the continence mechanism, is predominately based on the collaborative work by James Ashton Miller and John DeLancey et al. They provide a readily understood way to explain the continence mechanism: "the hammock hypothesis" (DeLancey, 1994), enhanced by a plethora of research performed in vivo as well as traditional anatomical descriptive studies. They attest that in its most simple, urine leakage will occur when bladder pressure is higher than urethral pressure. Maintaining continence during rises of IAP can be considered as reliant upon the functional co-ordination and neural control of two anatomical systems: the sphincteric closure system and the urethral support system (Ashton-Miller & DeLancey, 2007).

1.7.1 Sphincteric closure system

The constriction of the striated urogenital sphincter, urethral smooth muscles and the vascular elements within the submucosa are thought to provide the primary basis of continence (Figure 1.3 and 1.7) (DeLancey *et al.*, 2008). The urethrovaginal sphincter and the compressor urethrae compress the lumen along with the U-shaped loop of the detrusor smooth muscle. The striated urethral sphincter maintains constant tone and may provide additional continence protection by voluntary increases in tone (Gosling *et al.*, 1981).

1.7.2 Urethral support system:

The major extrinsic urethral supports are the anterior vaginal wall, endopelvic fascia, the deep part of the PFM (levator ani) and arcus tendineus fasciae pelvis (ATFP). The constant resting tone of the PFM also keep the urogenital hiatus closed (DeLancey & Hurd, 1998) and they act as a supportive structure maintaining the position of the bladder and proximal urethra within the intra-abdominal cavity.

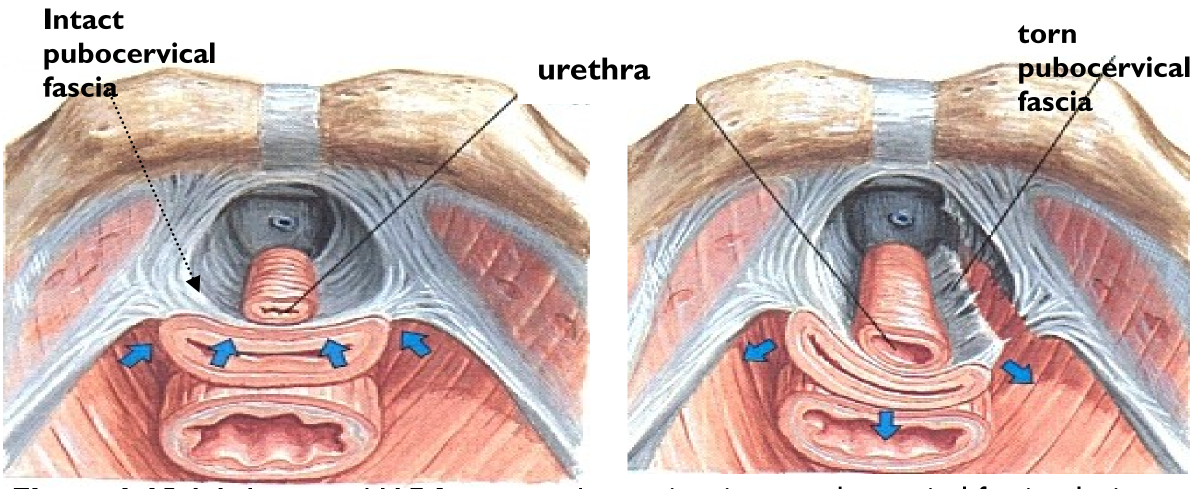

Figure 1.10 (a): Increased IAP forces urethra against intact pubocervical fascia, closing the urethra **(b)** Defective fascial support allows rotation and potential opening of the urethra due to increased IAP. Reproduced with permission from (Netter, 2006)

Richardson presented a concept of site specific, isolated breaks in pelvic connective tissue as a causative factor of prolapse and incontinence as opposed to the previous concept that the support tissues in the anterior vaginal wall had generally been stretched (Richardson *et al.*, 1976;Richardson, 1996) The 'hammock' hypothesis developed this concept (DeLancey, 1994) and stated that a combined muscle and fascial support provided a stable suburethral layer onto which the urethra was compressed during increases in IAP. The myofascial support therefore helped to close the urethral lumen, maintaining urethral closure pressure above rapidly increasing bladder pressure (Figure 1.10a). The stiffer the supporting hammock, the more resistance the urethra would have to the displacement created by increases in IAP. If there were breaks in the continuity of the endopelvic fascia or if the levator ani muscle was damaged, the supportive layer under the urethra would provide less resistance to deformation. Incontinence may then be provoked by the failure of the urethral lumen to close sufficiently (Figure 1.10b).

1.7.3 Functional integration

Urethral support and constriction is therefore provided by a coordinated action of fascia and muscles acting as an integrated unit under neural control. If any one of the subsystems is damaged, it seems possible for one of the other subsystems to compensate (Miller *et al.*, 1998;Dumoulin *et al.*, 2004b). Understanding which subsystem(s) is (are) responsible for incontinence has been difficult due to the lack of suitable quantitative instrumentation, therefore individualised treatment for the incontinent patient has also been lacking. Furthermore, it is no technique available that enables to differentiate definitively between those patients who will benefit from PFM re-eduacation and those who will not. For example, SUI may be due to urethral hypermobility (deficient urethral support system), and in this situation, if the PFM is normally innervated and are sufficiently attached to the endopelvic fascia, then it is known that some women can learn to use a voluntary muscle contraction during a cough to reduce the mobility of the urethra and help prevent urine loss (Miller *et al.*, 2008). If however, SUI is due to insufficient functioning of the striated urethral sphincter (deficient sphincteric closure system), then an active PFM contraction, or surgery aimed to reduce the mobility of the urethra, may not be able to sufficiently compensate for the lack of sphincteric closure. From a clinical and research perspective, greater understanding of the dynamic role of the PFM and urethral mechanics in maintaining continence is of value in understanding the pathophysiology and perhaps would improve the treatment outcome of women with SUI.

1.7.4 Treatment options for SUI

Several randomised controlled trials (RCT) and systematic reviews have confirmed that PFM training is an effective treatment for stress and mixed urinary incontinence and it remains the most common conservative treatment for women with SUI (Dumoulin & Hay-Smith, 2008). Successful conservative treatment has concentrated upon strength training of the PFM in addition to adding a PFM contraction prior to and during activities that increase intra-abdominal pressure (IAP) a termed coined "The Knack" as it implies a learned skill (Miller *et al.*, 1998;Dumoulin *et al.*, 2004b;Berghmans *et al.*, 1998). The Knack has been shown to be an effective treatment for selected older women with mild stress or mixed incontinence in a prospective, randomised, single-blind interventional study (Miller *et al.*, 1998). A more recent blinded randomised controlled trial indicated no significant difference between a programme using the Knack manoeuvre alone compared with the Knack plus PFM strengthening (Hay-Smith EJC. *et al.*, 2002). Further details regarding The Knack will be found in Chapter 8.

From the point of view of resolving whether patients should undergo conservative treatment for urinary incontinence or surgical treatment, judicious evaluation of the PFM is necessary. It is a clinical and researched observation that there are a significant number of incontinent women who have a strong pelvic floor (Morin *et al.*, 2004a;Theofrastous *et al.*, 2002)or greater pelvic floor muscle activity (Smith *et al.*, 2007a) and conversely a number of continent women with a weak pelvic floor (Miller *et al.*, 1998). Practically, from the clinicians' point of view, effective management depends on a reliable, specific functional PFM assessment. When it is clear that the patient is able to generate a balanced PFM contraction, however weak, they can be assured that their neuromuscular circuitry is intact and the prospect of improvement is possible. However if they have a strong PFM contraction, strengthening would seem a futile exercise, and correct co-ordinated timing of contraction could be considered (Miller *et al.*, 1998;Dumoulin *et al.*, 2004b;Devreese *et al.*, 2004;Smith *et al.*, 2007a). According to ultrasound studies (Miller *et al.*, 2001) not all females with SUI are able to displace their urethra with a PFM contraction and clinical observations of the author, suggest that there are subtle differences in the direction of displacement of the urogenital structures of some females when asked to contract their PFM. It still is necessary to establish whether the ability to support the urethra with a PFM contraction; which would be a product of both neuro-muscular and appropriate connective restraints, is a good indicator of successful PFM rehabilitation. It would however explain why when some women contract their PFM there is not an increase in intra-urethral pressure even though the strength of PFM contraction is good. It is expected that further examination of these observation will ultimately lead to a better classification of PFM function and can be used to select patients for the most appropriate treatment. However, when patients do not respond to conservative rehabilitation and are unable to accomplish a well timed, co-ordinated, balanced PFM contraction, the surgical option could be offered as it will minimize ineffective and futile physiotherapy.

There now follows a short review of current methods used to measure PFM function, although further details will be found in the corresponding experimental chapters, later in the Thesis.

1.8 Current clinical practice in pelvic floor muscle assessment:

Manual muscle testing, using one or two gloved lubricated fingers inserted into the vagina is the technique used by most clinicians to evaluate the strength of a PFM contraction, frequently using a 6 point modified Oxford Grading ordinal scale devised by Laycock (Laycock, 1992) (Table 1.1). This scale can also be applied to assessment of the PFM per rectum in men and women.

Table 1.1: Modified Oxford Scale for Digital Evaluation of PFM Strength

Grade	Description
0	Nil
1	Flicker
2	Weak
3	Moderate, slight lift of the examiners fingers, no resistance
4	Good, sufficient to elevate the examiners fingers against light resistance
5	Strong, sufficient to elevate the examiners fingers against strong resistance

In addition to strength, this vaginal PFM assessment also measures whether or not there is a correct lifting rather than bearing down contraction, the endurance of the contraction, the number of contractions necessary to overload the muscle and the ability to perform repeated quick contractions (Laycock & Jerwood, 2001). These additional measures are undertaken in order to produce a patient specific exercise programme for rehabilitation.

A number of studies have evaluated both the intra and inter-observer agreement of the Oxford scale, (Jeyaseelan *et al.*, 2001;Frawley *et al.*, 2006b) and indicated substantial agreement (K_w 0.69 to 0.86). However one study concluded that the method was not reproducible, sensitive and valid to measure PFM strength for scientific purposes, based on the results of Spearmans $r = 0.70$ $p < 0.01$ and un-weighted Kappa statistic of $K = 0.37$ (S.E.M = 0.16) (Bo & Finckenhagen, 2001). However neither statistical test in the study by Bo & Finckenhagen was optimal for judging reliability of the Oxford scale. It is possible to have a high correlation coefficient when agreement is poor, as correlation only states the linear relationship between two variables and is not an indicator of agreement (Bland & Altman, 1986). Furthermore, the categories within the Oxford Scale are ordered, that is, the first and second category has the same importance as a difference between the second and third category, consequently a weighted Kappa, with 95% CI is more appropriate (Bland & Altman, 1990).

The multidisciplinary group of the International Continence Society (ICS), the Pelvic Floor Clinical Assessment Group (PFCAG) suggested that the quantification of a voluntary PFM contraction was problematic and recommended the use of a four point scale, absent, weak, normal or strong (Messelink *et al.*, 2005) (Table 1.2).

Table 1.2: Recommended ICS voluntary PFM Scale

Grade	Description
Absent	No contraction is palpated or present
Weak	Weak contraction is palpated
Normal	Normal contraction is palpated
Strong	Strong contraction is palpated

Until recently this scale had not been validated nor tested for reliability (Slieker-ten Hove *et al.*, 2008). Slieker-ten Hove et al 2008, indicated that voluntary contraction of PFM had an intra-observer and inter-observer agreement of $K_w = 0.67$, (95% CI 0.46 to 0.81) and $K_w = 0.64$ (95% CI 0.48 to 0.77) respectively, which was poorer than the Oxford Scale reliability studies.

The PFCAG also suggested that other qualities of PFM function such as voluntary relaxation after contraction, involuntary contraction and relaxation of the PFM during an increase in intra-abdominal pressure (IAP) such as a cough should also be verified as part of a clinical assessment and should be recorded as being absent or present, in addition to any marked asymmetry or pain on palpation. Intra-observer reliability for the first digital assessment scheme of PFM function conforming to the ICS recommendations (Slieker-ten Hove *et al.*, 2008) was shown to be fair to good for these various categories ($K_w = 0.33$ to 0.76). Inter-observer reliability however for over 40% of the categories was generally poor ($K_w < 0.20$), for example palpation and movement of the perineum during a cough ($K_w = 0.03$ and 0.01 respectively) although it was good for the presence of pain during palpation ($K_w = 0.85$) and moderate for fast contractions ($K_w = 0.47$) and closing of the hiatus by PFM contraction ($K_w = 0.45$).

Some of the variability could have been attributed to fatigue of the PFM of the female volunteers being tested, as it appears that the sequence of testing was not randomised and the volunteers were examined four times in a period of an hour. The authors also attributed some of the poor inter-observer agreement to the number of scores on the rating scale of some items, the learning effect of the women being tested and the differences of observers themselves, such as tone of voice. It also appears that there was a significant degree of ambiguity regarding the interpretation of test scores. Perhaps with further training and discussion, improved reliability could have been attained; in addition, palpation categorizing results on 3 or 5-point scales may not have sufficient sensitivity to differentiate between individuals.

In the study by Slieker-ten Hove et al (Slieker-ten Hove *et al.*, 2008) there were also large differences in intra and inter-observer variability for symmetry of contraction (K_w = 0.64 and 0.16) respectively, which is in agreement with Devreese (personal communication 2002) who suggested that even after extensive discussion, testing and training, acceptable inter-observer agreement for symmetry could not be attained in their pilot studies, so a central measurement was used for their subsequent study (Devreese *et al.*, 2004)

Devreese also developed a visual inspection and digital palpation scale to examine other aspects of PFM function, (Devreese *et al.*, 2004) including the different anatomical components of the PFM, the effect of a cough on the perineum and the coordination with the abdominal muscles. The-inter and intra-observer reliability of Devreese et al measurement in 40 continent and 40 incontinent women (26 with SUI and 14 with mixed incontinence) is good to almost perfect in all categories. Visual inspection scale showed kappa values between 0.91-1.00, and tone percentage of agreement ranged from 95%-100%. K_w varied from 0.77 to 0.95 for strength and 0.87 to 0.88 for coordination between the superficial and deep part of the PFM. Agreement for coordination between the PFM and abdominal muscles during a voluntary PFM contraction and a cough varied between 0.94 and 0.97. Endurance and speed of the PFM contraction varied from 0.97 to 1.00. The reliability values in the study by Devresse et al are much higher than those in the previous studies reported which is most likely attributed to clear instructions, the detailed and well defined test procedures and scoring system. It also was the first study that focuses attention upon the assessment of the complex interaction of the PFM and abdominal musculature (Sapsford & Hodges, 2001) The main limitation of this method is the length of time the assessment takes, and the lack of ease with which most clinicians, other than physiotherapists, could incorporate it into their clinical practice.

As the PF is without direct visual access, and in addition is a complex arrangement of fascia and muscles, it is easy to comprehend the difficulties associated with accurately locating the same position to take a repeated measurement. In addition, the length of the examiner's finger, the variability, depth and size of the vaginal hiatus will further affect the location of palpation site. Muscle testing will therefore reflect a combination of factors such as whether there is intact muscle, neural and connective tissue components, as well as the resting muscle bulk, co-existing hyper or hypo activity as well the pressure exerted by the examiners' finger. The size of the levator hiatus; which will also be affected by a number of different pathologies such as connective tissue deficits, muscle deficits or inhibition; will also affect the displacement pressure generated. PFM avulsion has been shown to reduce the capacity of the muscle to narrow the hiatus (Otcenasek *et al.*, 2007) and even partial avulsion of a muscle from its insertion, has an effect on lift and contraction strength (Dietz & Shek, 2008).

Digital palpation is essentially a subjective measurement; the accuracy of manual muscle testing is dependent upon the experience and training and therefore interpretation of the results by the examiner. Inter-observer variability has to be established where there is more than one assessor as differences between observers are a potential threat to the validity of a study and cannot be controlled for in any study design. Where there is disparity further training and discussion is required to ensuring that any changes that do occur are due to the manipulation of the independent variable, and not due to the instrument (Finch *et al.*, 2002). With sufficient training and discussion, as indicated with two studies; (Jeyaseelan *et al.*, 2001;Devreese *et al.*, 2004) considerable agreement can be attained, however to date there remains considerable debate as to whether vaginal palpation of PFM strength or function has sufficient sensitivity and reproducibility for scientific purposes (Messelink *et al.*, 2005;Bo & Finckenhagen, 2001).

1.9 Current research methods of measuring PFM activity:

The inherent limitation of palpation to consistently enable the evaluation and progression of rehabilitation has, particularly for research purposes, resulted in many modalities to measure PFM activity, all of which have their own qualities, advantages and limitations (Bo & Sherburn, 2005).

A variety of trans-vaginal physical devices have been developed, including vaginal squeeze pressure measurements (manometers or perineometers) (Dougherty *et al.*, 1986;Bo *et al.*, 1990a);(Laycock & Jerwood, 1994); dynamometers (Dumoulin *et al.*, 2003) and instrumented speculums (Morgan *et al.*, 2005), which measure vaginal closure forces; the perfusion profilometer (Guaderrama *et al.*, 2005b) and the directional probe (Constantinou & Omata, 2007) which are able to measure both force and direction of displacement.

Manometric devices can be inserted either into the urethra, vagina or rectum and indirectly measure PFM strength and endurance by recording pressure change in centimetres of water. The reliability of manometry for PFM strength are reasonable, however have often been tested using correlation coefficients or tests of probability (Kerschan-Schindl *et al.*, 2002;Hundley *et al.*, 2005;Dougherty *et al.*, 1986;Bo *et al.*, 1990a;Laycock & Jerwood, 1994;Wilson P *et al.*, 1991) although later studies have shown excellent reproducibility (95% C.I. 0.90 to 0.99) (Frawley *et al.*, 2006b). Both the reproducibility and validity of the measurement is primarily affected by the positioning of the device and the inability of the device to give any indication of the origin of the applied force. For example, any increase in intra-abdominal pressure (IAP), such as during a Valsalva instead of a PFM contraction, or contraction of other adjacent muscle groups will affect the pressure reading (Peschers *et al.*, 2001b). Some authors have suggested that a valid measurement can be recorded as long as a correct inward direction of the PFM contraction is simultaneously observed (Bo *et al.*, 1990b;Bump *et al.*, 1996). Correlations between digital palpation and perineometer recordings are variable (95% C.I = 0.33 to 0. 86) (Hundley *et al.*, 2005;Isherwood & Rane, 2000;Laycock & Jerwood, 1994;Uyar *et al.*, 2007). Comparison between studies is challenging due to differing technical parameters and diameters of the probes, particularly as more recent dynamometric studies have indicated that the size of the vaginal probe alters muscle function (Dumoulin *et al.*, 2003).

Dynamometers or instrumented speculums are inserted into the vagina and voltage values from the strain gauges are amplified, digitised and converted into units of force (Newtons). The resultant forces exerted by the PFM on the dynamometer are measured in the anterior-posterior direction (Dumoulin *et al.*, 2003;Morgan *et al.*, 2005) or in the transverse (Verelst & Leivseth, 2004b) direction at different openings of the speculum, allowing measurement at various PFM muscle lengths. Although theoretically they have the same disadvantage as manometers, in that the force measured by the dynamometer also can be affected by IAP rises or contractions of other muscle groups;

the influence of IAP on PFM measurement was proven to be negligible (Morin *et al.*, 2006). Good and very good test-retest reliability studies of strength, speed of contraction, endurance and passive properties of the PFM in both continent and incontinent women have been indicated (Dumoulin *et al.*, 2004a;Morin *et al.*, 2004c;Miller *et al.*, 2007;Morin *et al.*, 2008) (intraclass correlation coefficient (ICC) of 0.73 to 0.86). Significant correlations were found between dynamometric measurements and digital testing using the Oxford Scale with coefficients of r = 0.727, r = 0.450, and r = 0.564 for continent, incontinent, and all women, respectively (Morin *et al.*, 2004b). The dynamometer is also able to discriminate between incontinent and continent postpartum women (Morin *et al.*, 2004a;Verelst & Leivseth, 2004a) in addition to pre and post treatment postpartum women (Dumoulin *et al.*, 2004b). Studies assessing the comfort and tolerance of the dynamometer in incontinent and continent women have also confirmed that the instrument and procedure are acceptable and painless (Dumoulin *et al.*, 2004a).

Although there are many excellent psychometric qualities of the dynamometer, it has no spatial resolution to localise the zone upon which the forces are imposed by the passive properties of the PF or PFM contraction. Recently, Guaderrama (Guaderrama *et al.*, 2005b) et al. described a vaginal pressure profile (VPP) using infusion manometry and a motorized pull-through technique. They demonstrated that the peak pressure was located at 2cm from the introitus of the vagina at rest and it increased significantly during a PFM contraction. However, they were unable to determine accurately how much the PFM contraction contributed to generate the vaginal closure pressure as they could not distinguish the closure pressures from different directions around the vaginal wall (Peng *et al.*, 2007b). To this end, Constantinou and Omata (Constantinou & Omata, 2007) designed a prototype directionally sensitive intra-vaginal PF probe, capable of measuring PF closure during voluntary and reflex generated PFM contractions. Further discussion of this pilot study is found in Chapter 7.

Many of these intra-vaginal devices quantify strength and or endurance of the PFM, however as discussed earlier there is indirect evidence to suggest that the contractile strength alone may not play as pivotal a role as previously thought in maintaining continence and timing of the PFM contraction may also be of primary importance (Dumoulin *et al.*, 2004b;Hay-Smith EJC. *et al.*, 2002;Barbic *et al.*, 2003;Delancey & Ashton-miller, 2004).

Electromyography (EMG) studies suggested that individual muscle activation patterns in SUI parous women were in principle similar to those observed in continent nulliparous women (Deindl *et al.*, 1994), although there was inhibition of motor unit firing on coughing and dissociated recruitment of motor units during voluntary and reflex activation in half of the incontinent group. Others have indicated that activation of the PFM precede the increase in bladder pressure measurement and contraction of other muscles involved in the cough reflex of continent women whereas PFM activity was delayed in women with SUI (Constantinou & Govan, 1982;Barbic *et al.*, 2003;Deffieux *et al.*, 2007). Smith et al (Smith *et al.*, 2007a) also provided evidence of delayed PFM EMG activity in incontinent women during rapid shoulder flexion and extension although postural PF EMG amplitude was greater in women with incontinence. In a further study however, women with incontinence demonstrated increased PFM EMG activity compared to continent women both prior to and during the postural response associated with unexpected loading (Smith *et al.*, 2007b). Interpreting what the electrical activity of a muscle is reflecting, in terms of magnitude or direction of force generation, is difficult (Turker, 1993). EMG activity can increase with an elevating or straining PFM contraction (Thompson, 2006) so this problem is particularly exaggerated in the PFM where their action is not visible.

Ultrasound imaging (USI) allows the operator to “see” the structures being imaged, and the next chapter describes the basic principles of ultrasound imaging together with a structured review of the literature is presented regarding the current research and clinical methods utilised in evaluation of the PFM using ultrasound, particularly in reference, but not restricted to, stress urinary incontinence (SUI).

2 Ultrasound imaging of the pelvic floor

2.1 Introduction

Ultrasound imaging (USI) has traditionally been used in the medical field by radiologists, sonographers and radiographers in a diagnostic capacity to evaluate disease or injury, or assist in biopsy and other medical procedures. Since the 1990's the use of USI has grown in popularity with physiotherapists to evaluate muscle structure and function and assist as a biofeedback tool (Whittaker *et al.*, 2007a). It is beyond the general scope of physiotherapy practice to diagnose pathology without validated training so in the first international meeting in May 2006, the scope of practice for physiotherapists using ultrasound was defined and agreed upon. "The term rehabilitative ultrasound imaging (RUSI) was used to describe the procedure used by physical therapists to evaluate muscle and related soft tissue morphology and function during exercise and physical tasks. RUSI is used to assist in the application of therapeutic interventions aimed at improving neuromuscular function. This includes providing feedback to the patient and physical therapist to improve clinical outcomes. Additionally, RUSI is used in basic, applied, and clinical rehabilitative research to inform clinical practice. Currently, the international community is developing education and safety guidelines in accordance with World Federation for Ultrasound in Medicine and Biology (WFUMB). Dated: 10 May, 2006"(Teyhen, 2006).

Since the 1980's ultrasound has been utilized to investigate and evaluate the female pelvic floor (PF). In this chapter, the basic principles of ultrasound imaging are described followed by a systematic review aimed to appraise and summarise the published evidence relating to the current ultrasound measurement methods and their application for the female PF particularly associated, but not limited to SUI. The aims of the current investigation and the primary hypotheses are then described with an outline of the remaining thesis.

2.2 Physical principles of ultrasound imaging

The following section outlines the basic principles, modes and applications of ultrasound imaging.

2.2.1 Basic Principles: In its simplest terms, pulses of high frequency sound waves (greater than 2MHz, primarily in the range of 3.5 to 15 MHz) are emitted by an ultrasound transducer (Figure 2.1) into the body, and parts of this energy are reflected (echoed) back, by various tissue densities (interfaces) towards the transducer. These echoes are then detected by the transducer and processed electronically for imaging. The transducer is therefore responsible for generating the ultrasound waves, receiving the echoes reflected back and converting them into electronic signals. Ultimately, the scanning angle and plane of ultrasound beam will determine the orientation and view of the structures being imaged.

Linear, sector, and curved array are three formats of a transducer that determine the shape and field of view. Linear array transducers produce rectangular images and have a wide near field, appropriate for imaging small superficial structures. Curved array transducers produce a curved, diverging image and have a wide far field (Figure 2.1).They are optimally used when the sonographic window is large, such as the pelvic floor. There are a number of different transducers typically used in imaging of the PF. Transvaginal (TV) or transrectal (TR) transducers are placed inside the vagina or rectum; transperineal (TP) and translabial (TL) are placed outside, either on the perineum or labia (Figure 2.1) and transabdominal (TA) are placed on the abdomen (Figure 2.3).

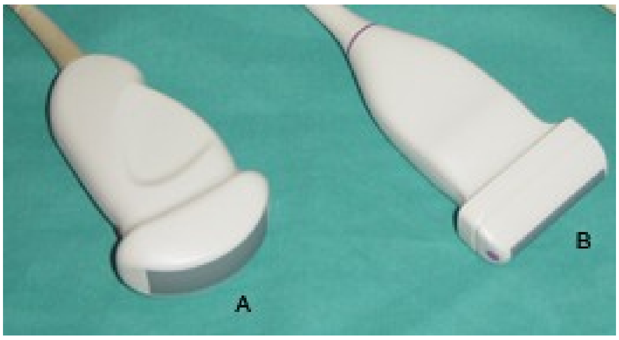

Figure 2.1: Curved (A) and linear (B) array transducers provide differing shapes in the ultrasound field-of-view.

How far the sound wave spreads (propagates) and how much is reflected back depends upon the strength of the transducer and the characteristics of the tissues it encounters (Kremkau, 2002). How deep the sound wave penetrates is also dependent upon the frequency, speed and intensity of the sound wave. The intensity of the sound wave is dependent on the size and power of the transducer: the stronger the intensity, the deeper the penetration. The speed at which the ultrasound wave travels also depends upon stiffness of the structure being imaged: the stiffer the structure (for example bone), the faster the propagation. Lower frequencies have the ability to penetrate further, or image deeper into the body, but the detail of the image is sacrificed as there is less resolution. The lower the frequency, the lower the attenuation (loss of intensity): the higher the frequency, the higher the reflection and greater detail imaged. So the choice of frequency is therefore a trade-off between spatial resolution of the image and imaging depth. It is advised to use the highest frequency transducer capable of viewing the tissues of interest (Hedrick, 2004). Typically a frequency of 3.5 to 5.0 MHz is required to view the PF and bladder using TP ultrasound, whereas TR or TV transducers typically are able to use a frequency of 7.0 to 10.0 MHz as the ultrasound beam is closer to the tissues being examined.

The propagating sound wave will pass through tissues of varying densities, and the images reflected back and viewed on the screen will also represent the differences in tissue resistance to the sound wave (acoustic impedance). The strength of the echo reflected back is proportional to the amount of acoustic mismatch between the structures; the greater the mismatch, the brighter the image on the screen. For example, bone has a particularly large acoustic difference with soft tissue, so the interface between bone and soft tissue will appear bright (hyperechoic) as most of the sound wave will be reflected back (Figure 1.12). High frequency ultrasound does not penetrate bone effectively (bone weakens or attenuates the sound wave); so deep to the bone, the screen will generally be dark (hypoechoic) or black (anechoic).

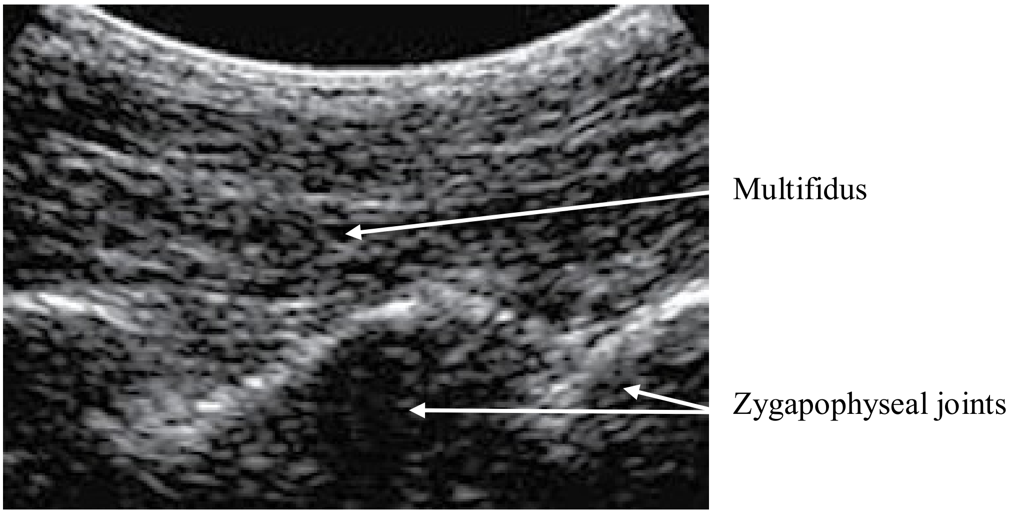

Figure 2.2: A parasagittal ultrasound image using a curved linear array transducer of the multifidus muscle in the plane of the zygapophyseal joints. At the muscle-bone interface the image appears bright (hyperechoic) and deep to the bone, the image is black (anechoic) or dark (hypoechoic).

In addition to the difference in tissue impedance, as mentioned earlier, the reflection is also dependent upon the direction of the ultrasound wave; an ultrasound wave that is perpendicular to the tissue being imaged will create a brighter reflection, as there will be less scattering (refraction) of the sound wave. In practical terms this means that the operator needs to adjust the angle of the transducer in order to create the clearest image, depending on the orientation of the structures being viewed. This can be particularly relevant when a patient performs a manoeuvre (such as a cough or PFM contraction) that displaces the tissue being imaged. The operator has to be skilled enough to subtly adjust the transducer to maintain optimum orientation of the wave form, and therefore maintain image clarity.

2.2.2 Modes of USI

The two most common modes of ultrasound in RTUS are "B" (brightness, brilliance) and "M" (motion, movement) mode. **B-mode** generates a cross sectional, large field of view from the whole length of the transducer (Figure 2.3A), allowing the visualisation of several structures at once. It can display their morphology and their positional relationship at any instant, including the changes due to a dynamic event such as a muscle contraction.

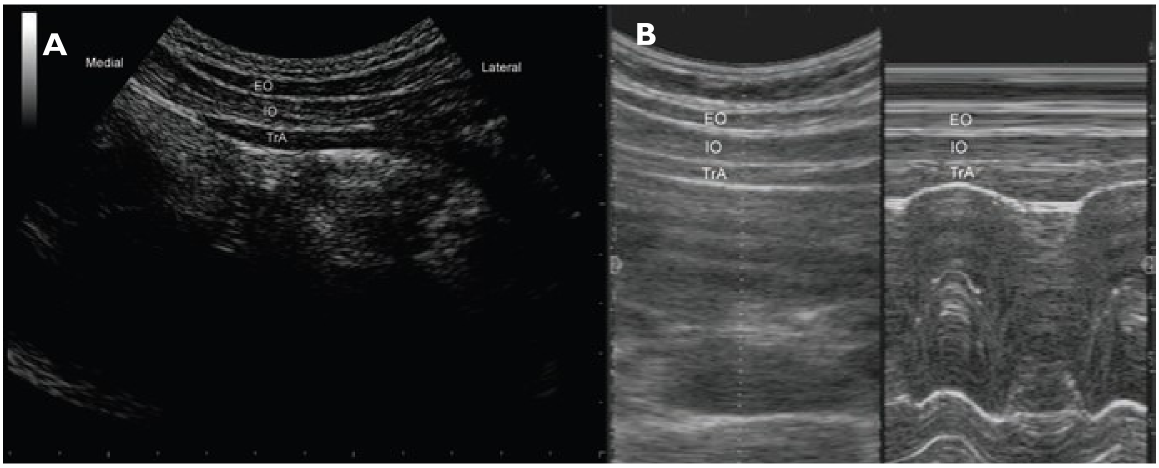

Figure 2.3: (A) A brightness mode (b-mode) image of the lateral abdominal wall. Abbreviations: EO, external oblique; IO, internal oblique; TrA, transversus abdominis. (B) A split-screen image with b-mode on the left and motion mode (m-mode) on the right. The m-mode image represents the information from the dotted line on the b-mode image displayed over time (x-axis). Static structures produce straight interfaces while structures that change in thickness or depth (in this case the TrA) create curved interfaces. The increase in depth of the TrA correlates to a contraction. Reproduced with permission (Whittaker, 2007).

M-mode however displays information from the midpoint of the transducer as a continuous image over time (represented by the dotted line on Figure 2.3B), illustrating changes in thickness or depth of a structure. The image in Figure 2.3B compares the different modes evaluating the change in thickness of the transversus abdominis muscle from a resting position to contracted state.

2.2.2.1 **High frame rate m-mode imaging** is able to capture 500 frames per second as compared to a frame rate of between 25 and 50 for conventional m-mode imaging. High frame rate USI has been shown to have comparable accuracy to intra-muscular EMG when detecting the onset of lumbar multifidus activity in healthy individuals (Vasseljen *et al.*, 2006).

2.2.2.2 **Volume or 3 dimensional (D) imaging** works using B mode ultrasound but instead of the ultrasound waves being directed from one angle as in 2D imaging, they are directed from multiple angles. The waves are reflected back and captured providing enough information to construct a 3D image in much the same way as 3D movies. Up until recently, 3D and 4D Ultrasound (real-time acquisition of volume ultrasound data) has been used predominately in obstetric settings to visualise the foetus (Benacerraf *et al.*, 2005).

2.2.2.3 **Doppler ultrasound** is a mode of ultrasonography that makes use of the Doppler effect in measuring whether structures (usually blood) are moving towards or away from the transducer and its relative velocity. It has been used to measure velocity, tissue strain and strain rates of the heart (Heimdal *et al.*, 1998) and gastric contractions (Gilja *et al.*, 2002) and more recently applied to measure the PFM in continent and SUI women (Oliveira *et al.*, 2007). A recent study also measured the strain rate and onset of abdominal muscle activity, indicating the potential for high frame rate m-mode USI to offer non-invasive alternatives to intramuscular EMG (Vasseljen *et al.*, 2009). Deformation and velocity imaging can be directly measured from conventional ultrasound or Doppler data; however strain and strain rate require post processing which requires access to the raw ultrasound signal and precludes real-time feedback (Whittaker *et al.*, 2007a). Other methods that require post-processing of the ultrasound signal to measure tissue displacement, velocity and deformation are speckle tracking and elasticity imaging (elastography).

2.2.2.4 **Elastography** is an ultrasonic method for imaging the mechanical properties of compliant tissues, originally by slightly compressing the tissue with the transducer while images were acquired (Ophir *et al.*, 1991). It has been utilised to detect tumours within the breast and prostate by objectively recording the increased stiffness of a cancerous lesion within the softer normal tissue (Cespedes *et al.*, 1993;Cochlin *et al.*, 2002). In musculoskeletal medicine, uses have included measurement of soft tissue displacement and strain caused by external forces including tension, compression, acupuncture needles and electrical stimulation (Gennisson *et al.*, 2003;Han *et al.*, 2003;Langevin *et al.*, 2007;Farron *et al.*, 2009).

2.2.2.5 Speckle tracking searches for a predefined region (kernel) of speckle pattern within one frame of the ultrasound image then searches for a similar speckle pattern in the next frame and so on. The unique speckled pattern is generated by the reflecting structures scattering the sound waves in random directions and the interference pattern they create (Stoylen, 2008). The speckle pattern will not repeat perfectly due to true out of plane motion and to small changes in the interference pattern, but as long as the frame rate is quick enough and/or the tissue being tracked does not move too quickly, the changes will be small from one frame to the next and speckle tracking can effectively define the motion of the tissue (Insana *et al.*, 1986). Speckle tracking has been successfully described in muscle tissue, liver and fat (Chen *et al.*, 1995). However with the exception of two very recent studies in which a contraction of the biceps brachii was described (Deffieux *et al.*, 2008) and the strain of the tendon of tibialis anterior calculated during a voluntary contraction (Farron *et al.*, 2009), to date speckle tracking has been used predominately in echocardiology.

2.3 Structured Review

This structured review was aimed to appraise and summarise the published evidence relating to the current ultrasound measurement methods and their application for the female PF particularly associated, but not limited to SUI.

2.3.1 *Search Strategy:* The online bibliographic databases Ovid MEDLINE (R) (1950 to 2009), and EMBASE Classic + EMBASE (1947 to 2009) were used to obtain the literature. The following keywords were used for the search as text words or subject headings using OVID software, and a paper was included if a word from: (ultrasound) OR (sonographic) AND (pelvic floor) OR (levator) OR (urinary incontinence) OR (pelvic organ prolapse) was found anywhere in the title or abstract or used as a MeSH heading.

The search results were limited to female, humans and reports in the English language. Duplicate papers were identified and deleted leaving 544 for evaluation. The remaining papers were assessed for relevance on the basis of the abstract, or if the abstract was not available then the title only. 150 papers were identified as being relevant to the structured review as they considered the evaluation of the female PF using real time ultrasound and full copies were obtained. For ease of evaluation, the review is presented in sections related to the transducer type utilised.

2.3.2 2D Transperineal (TP) imaging or translabial (TL) ultrasound offer comprehensive information regarding the PF and is an established method for clinical and research evaluation of women with prolapse, incontinence and continent controls (Koelbl *et al.*, 1988;Gordon *et al.*, 1989;Bernstein *et al.*, 1991;Wijma *et al.*, 1991;Schaer *et al.*, 1995;Peschers *et al.*, 1996;Dietz & Wilson, 1998;Howard *et al.*, 2000;Reddy *et al.*, 2001;Miller *et al.*, 2001;Morkved *et al.*, 2004;Thompson *et al.*, 2005;Tunn *et al.*, 2005;Costantini *et al.*, 2006;Peng *et al.*, 2006;Jones *et al.*, 2006;Peng *et al.*, 2007a). Due to their non-invasive nature, ready availability and the defined scope of physiotherapy practice, the TP and transabdominal (TA) approaches are used most widely by physiotherapists.

2.3.2.1 Technique of TP ultrasound: The ultrasound transducer is placed on the perineum in a mid sagittal direction, orientating the transducer so that the clearest images of the bladder, urethra, rectum and symphysis pubis (SP) are viewed (Figure 2.4).

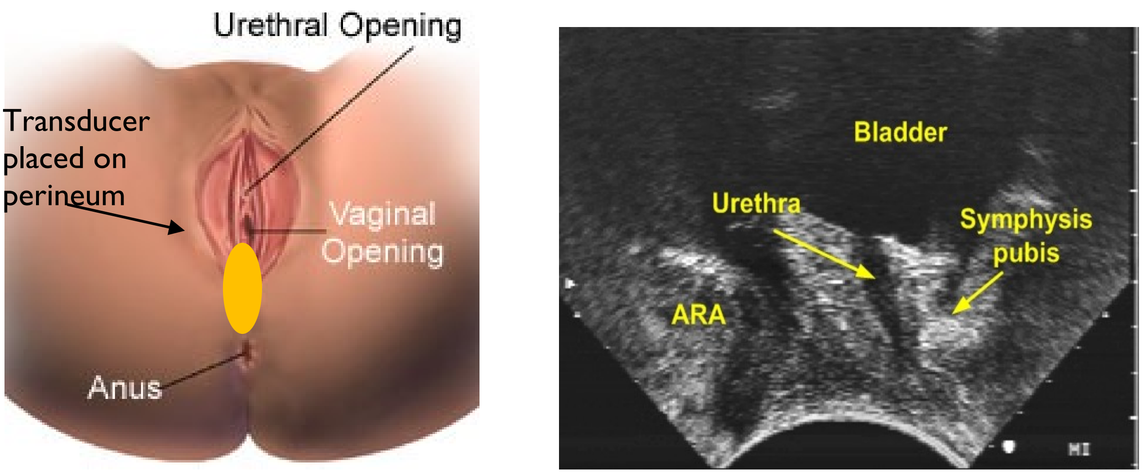

Figure 2.4: (a) Mid sagittal position of transducer during transperineal (TP) imaging; **(b)**Typical TP view with ano-rectal Angle (ARA), urethra, bladder and Symphysis Pubis.

Although the exact position of the transducer on the perineum is dependent on the ultrasound image viewed, reliable techniques have been established for this approach

(Schaer *et al.*, 1996;Peng *et al.*, 2007a). TP imaging is influenced by the amount of pressure applied by the transducer: the operator has to apply sufficient pressure to the transducer so that a clear image is viewed, but not enough to distort or support the pelvic organs during the manoeuvres (Schaer *et al.*, 1996).

Patient positioning has also been documented to affect the position of the urethra, so must be stated (Schaer *et al.*, 1996;Dietz & Clarke, 2001a). However disagreement exists on whether the amount of bladder volume affects the mobility and position of the bladder. Dietz and Wilson suggest that a nearly empty bladder exhibits greater mobility of the bladder neck and proximal urethra (Dietz & Wilson, 1999), whereas Schaer et al suggest that increasing bladder filling does not affect the measurement values and best images are observed with a bladder volume of approximately 300mls (Schaer *et al.*, 1996). Consequentially, the bladder filling protocol utilised also needs to be recorded.

2.3.2.2 Current quantitative measurements of TP ultrasound: Several measurement systems for TP or transvaginal/rectal imaging have been devised to quantify position and mobility of the PF on ultrasound scans, but all rely upon the drawing of a reference line either through the central line of the symphysis pubis (SP) or its inferoposterior margin (Figure 2.5, 2.6) (Creighton *et al.*, 1992;Mouritsen & Rasmussen, 1993;Schaer *et al.*, 1995;Chen *et al.*, 1997;Dietz & Wilson, 1998;Reddy *et al.*, 2001;Pregazzi *et al.*, 2002;Yalcin *et al.*, 2002).

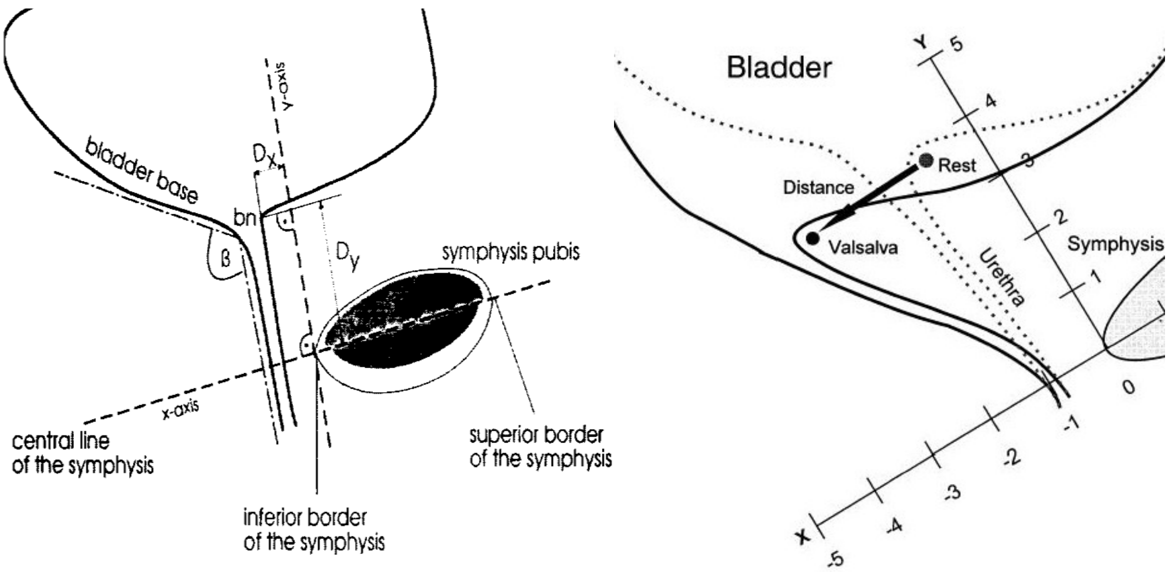

Figure 2.5: Measurement method for perineal ultrasound, vesical neck position at rest and during Valsalva. D_x = distance between y axis and bladder neck (BN); D_y = distance between x axis and BN; β = posterior urethrovesical angle. Reproduced with permission (Schaer *et al.*, 1995).

Relative to this fixed reference point, the resting position and/or angle β of the urethra, bladder base and more recently the ano-rectal angle (ARA) (Huang et al., 2006;Costantini et al., 2006), the displacement at the end of events such as a voluntary PFM contraction, Valsalva and coughing is calculated. Without correcting for transducer movement relative to the symphysis pubis, the percentage errors in measurement range from 18-87% (Reddy et al., 2001).

In addition to assessing PF movement during a variety of manoeuvres in a diagnostic capacity; introital and perineal ultrasound has also been used to assess the position and mobility of the BN and PF before and after surgical intervention for SUI and prolapse (Martan *et al.*, 2002;Sarlos *et al.*, 2003;Viereck *et al.*, 2004;Lo *et al.*, 2004). It can be a prognostic indicator of surgical intervention, provide insight into the mechanisms of therapeutic change and can evaluate causes of functional disturbances, such as haematomas, misplacement or displacement of surgical tape or mesh (Lo *et al.*, 2001;Tunn *et al.*, 2004;Viereck *et al.*, 2006).

TP Ultrasound has been used to quickly facilitate an elevating voluntary PFM contraction in women who were initially unable to do so (Dietz *et al.*, 2001). Between 25 to 57% of individuals with incontinence or prolapse have difficulty producing a lifting PFM when provided with verbal and/or tactile facilitation alone (Bump *et al.*, 1991;Dietz *et al.*, 2001;Thompson & O'Sullivan, 2003). Ultrasound seems to be a clinically valuable biofeedback tool and adjunct to conservative rehabilitation, but this has yet to be confirmed under research conditions.

Bernstein calculated the resting and contracted thickness of the PFM in healthy and incontinent women, and also that of incontinent women after training (Bernstein, 1997). There were no significant differences in muscle thickness between groups of continent and incontinent women. In healthy women, the median value of PFM thickness at rest and during contraction was 9.8mm (range 7.7-11.7) and 11.2mm (range 8.5-13.0) respectively. The values in incontinent women were 9.2mm (range 6.7-11.3) and 10.2mm (range 7.0-12.7) before training and 9.7mm (range 7.8-11.7) and 11.2 (range 9.2-13.2) after training. However in a more recent study, Morkved et al determined that continent women had significantly thicker muscles at rest (P= 0.018) and with contraction (P=0.006) compared to incontinent women. Their values and range were generally smaller than the earlier study. In healthy women the median value of PFM thickness at rest and during contraction was 7.15mm (range 6.82-7.48) and 9.41mm (range 9.00-9.82) respectively.

The values in incontinent women were 6.34mm (range 5.76-6.93) and 8.20mm (range 7.46-8.95). The discrepancy in muscle thickness between the two studies may be due to differences in the study populations, but may also be due to different measurement techniques as the latter study did not include the thickness of both the superficial and deeper layers of the PFM.

2.3.2.3 Reliability and specificity of TP ultrasound: Although various approaches have been developed to assess the value of quantifying urethral mobility on 2D TP ultrasound there is disagreement regarding both the intra and inter observer reliability of measuring bladder neck (BN) position and displacement (Schaer *et al.*, 1995;Reddy *et al.*, 2001;Peschers *et al.*, 2001a;Masata *et al.*, 2005;Tunn *et al.*, 2005;Armstrong *et al.*, 2006;Braekken *et al.*, 2008;Toozs-Hobson *et al.*, 2008;Gottlieb *et al.*, 2009;Majida *et al.*, 2009).

Test-retest reliability for BN displacement during a cough and Valsalva have been reported as excellent reporting intraclass correlation coefficient (ICC) and 95% confidence intervals (CI) (ICC 0.96 , 95% CI 0.90 to 0.98, Bland and Altman mean difference ($\bar{d}$) 0.1cm and Standard deviation of the difference (SD_{diff}) 0.2cm)(Peschers *et al.*, 2001a) . Yet another more recent study has indicated moderate test-retest reliability for a cough with very wide CI (ICC 0.51; 95% CI 0.00 to 0.84) (Braekken *et al.*, 2008;Peschers *et al.*, 2001a;Hoff Brækken *et al.*, 2009). Test-retest reliability was also calculated using an unnamed correlation coefficient and indicated values of 0.93 for a cough, 0.85 for Valsalva and 0.91 for a voluntary PFM contraction (Reddy *et al.*, 2001). Another study has also reported very good reliability indices (ICC and standard error of measurement (SEM)) for both Valsalva (0.87(0.16)) and PFM contraction (0.91(0.11)) (Dietz *et al.*, 2002;Thompson *et al.*, 2005;Sherburn *et al.*, 2005;Thompson *et al.*, 2007). These values were similar to those reported in a very recent study for both Valsalva (ICC 0.82; 95% CI 0.53 to 0.93) and PFM contraction (ICC 0.79; 95% CI 0.43 to 0.92)(Gottlieb *et al.*, 2009).

Up until very recently, there had only been one TP ultrasound measurement study devised to quantify BN position and mobility on ultrasound that had reported to have good inter-observer reliability (Schaer *et al.*, 1995;Chen *et al.*, 1997;Bai *et al.*, 2004). However, the inter-observer reliability values by Schaer et al; which are often cited for evidence of reliability of TP ultrasound evaluation of the PF, measure the resting position of the BN and at the end of Valsalva (Schaer *et al.*, 1995). Their results report the mean differences between examiners and that the differences are not statistically significant. Another similar study (Masata *et al.*, 2005) concludes that the technique is not reproducible, quoting mean differences and their statistical significance. However, the use of t-tests for reliability analysis is questionable as two very different sets of data could have the same mean.

In additional to the use of questionable statistical analysis, it was suggested that differences between the operators could be due to different placement of the axis of the symphysis pubis (SP), which is the reference point from which the static measurements are taken, and has been shown to be a significant source of error (Reddy *et al.*, 2001;Armstrong *et al.*, 2006). In order to overcome the difficulties associated with the variance in assigning the reference point on the SP and to devise a measurement of BN position and mobility with acceptable levels of intra- and inter-observer reliability; a SP template, drawn onto an acetate sheet containing x and y axes, was placed over scans, by aligning the x-axis with the SP central axis (Reddy *et al.*, 2001;Armstrong *et al.*, 2006). The group discovered that accurate reliability assessment of all conditions required Bland and Altman analysis; and the designation of the pubic bone central axis remained a source of variance between investigators. Another potential source of error during measurement of displacement, was accurately determining the finishing point of the manoeuvre, particularly those that were fast, such as coughing. Even with the ability to slow down video recordings, the operator has either had to make multiple on-screen measurements, and determine the exact peak moment, or end position of the manoeuvre, freeze it, and then measure the change in position manually on screen or with built in electronic callipers. To date, no study has reported the inter-observer reliability of a cough measurement by ultrasound.

More recently, the angle the rectal ampulla forms with the anal canal, the ano-rectal angle (ARA) has become the target of analysis in PF dysfunction (Beer-Gabel *et al.*, 2002;Peng *et al.*, 2006;Costantini *et al.*, 2006;Jones *et al.*, 2006;Huang *et al.*, 2006;Peng *et al.*, 2007a). The central sling component of the PFM, puborectalis and pubococcygeus, wraps around the anorectal junction, and its displacement is thought to be closely associated with a PFM contraction (Costantini *et al.*, 2006). Very recently, one 2D TP study has evaluated the reliability of measuring the displacement of the ARA during a Valsalva and a PFM contraction (Gottlieb *et al.*, 2009). ICC of the displacements for

Valsalva (ICC 0.90; 95% CI 0.73 to 0.97) and PFM contraction (ICC 0.72; 95% CI 0.24 to 0.89) were good to excellent, although the CI was wide for the PFM contraction and the SEM for displacement during Valsalva was the highest recorded in their study (0.79cm).

Two 2D TP studies have also reported at least acceptable intra-observer reliability of measuring the thickness of the PFM (Morkved *et al.*, 2004). Morkved et al reported excellent intra-observer reliability (ICC = 0.9841: n =50) and good inter-observer reliability (ICC = 0.7123: n= 23).

Measurement of the resting position of the urethra and its displacement at the end of a manoeuvre, has so far, not been shown to be specific for SUI (Schaer *et al.*, 1995;Chen *et al.*, 1997;Bai *et al.*, 2004). However the degree of rotation and angle change β of the BN at rest and at the end of a Valsalva has been shown to be a sensitive (96%), and specific (92%) measure for detecting SUI, (positive predictive value (85%), negative predictive value (98%)) (Pregazzi *et al.*, 2002). Chen et al also found that if the parameters of BN mobility and the change in urethral angle were combined, the specificity and positive predictive value for SUI were 83.1% and 67.6% (Chen *et al.*, 1997). However the inter-observer reliability of β angle is only reported for the angle at rest, not after the manoeuvre (Bland and Altman $\bar{d}$ 0 degrees and 95% of the differences between -3 →+3 degrees). The authors report difficulty obtaining this measure during manoeuvres due to considerable distortion of the urethra. They only report the change of angle during a Valsalva; however they do not report the reliability of this measure.

2.3.2.4 Validity and correlation with other methods of PFM assessment: To date, no study has compared displacement of the ARA to PFM strength measurements. There is a moderate to good correlation between PFM strength measured with vaginal squeeze pressure and muscle thickness (r = 0.70) (Morkved *et al.*, 2004). There has been a fair to moderate correlation between displacement of the BN to strength of PFM contraction measured by digital palpation (r = 0.52 to 0.58) and vaginal squeeze pressure (r = 0.38 to 0.43) (Dietz *et al.*, 2002;Thompson *et al.*, 2006b).

Other tests to establish the validity of 2D ultrasound with respect to measurement of the morphology of the PFM and anatomic assessment and mobility of the bladder neck have also been determined using MRI (Mouritsen, 1997) and videocystourethrography (a form of radiological imaging) (Koelbl *et al.*, 1988;Gordon *et al.*, 1989;Schaer *et al.*, 1995;Dietz & Wilson, 1998). To date, no studies have described the relationship between the amount of EMG activity of the PFM and UVJ elevation or change in thickness of the PFM.

2.3.2.5 3D Transperineal ultrasound imaging: 2D ultrasound imaging is unable to analyse out-of-plane structures and therefore accuracy of the image analysis is affected. In addition, 3D imaging can produce images in both the axial as well as the midsagittal planes. It permits direct imaging of the levator hiatus, the levator ani, paravaginal supports, and detailed images of the urethra, urogenital and anal sphincters as well as implants used in pelvic floor reconstruction and surgery (Stuhldreier *et al.*, 1997;Wisser *et al.*, 1999;Umek *et al.*, 2002;Dietz *et al.*, 2005;Verhey *et al.*, 2005;Dietz *et al.*, 2006;Huang *et al.*, 2007;Kruger *et al.*, 2008;Yang *et al.*, 2009;Weinstein *et al.*, 2009). As a research tool, it is gaining popularity in the field of obstetrics and gynaecology, as it produces views previously only available using magnetic resonance imaging (MRI) although as described later, a 2D TV technique with a scanning angle of 360 degrees has also enabled measurement of the levator hiatal area similar to those obtained by MRI (Athanasiou *et al.*, 2007).

3D ultrasound indicates that voluntary PFM contraction influences the morphology of the female urethra by external compression of the urethra, rather than contraction of the sphincter muscle (Umek *et al.*, 2002). Although moderate to good intra and inter-observer reliability has been shown with measurement of hiatal area, diameter, length and PFM thickness (ICC values between 0.57-0.97), variable reliability has been shown with the shortening of PFM area, hiatal transverse distance and muscle length during contraction (ICC values between 0. 37 and 0.68)(Weinstein *et al.*, 2007;Braekken *et al.*, 2009). There is only a weak association between Oxford grading and reduction in hiatal dimensions on contraction ($r = -0.32$, $P = 0.024$) and poor agreement between vaginal palpation of PFM defects and 3D/4D imaging (Dietz *et al.*, 2006). Compared to MRI, vaginal examination also underestimates these defects (Kearney *et al.*, 2006).One recent study has estimated inter-observer reliability, correlation and agreement between MRI and 3D ultrasound using tests of ICC and Bland-Altman analysis (Kruger *et al.*, 2008). It indicates fair to excellent inter-observer repeatability for all parameters measured with both methods (ICC) and moderate to substantial agreement for all parameters (ICC 0.587-0.783).

2.3.3 Transvaginal (TV) and transrectal (TR) ultrasound transducers provide an opportunity to get closer to the pelvic organs, providing clearer, more detailed images than a TP or Transabdominal (TA) view and consequentially can be superior in a diagnostic capacity (Quinn *et al.*, 1988;Deen *et al.*, 1993;Athanasiou *et al.*, 1999;Wisser *et al.*, 1999;Toozs-Hobson *et al.*, 2001;Umek *et al.*, 2001;Sarnelli *et al.*, 2003;Reisinger & Stummvoll, 2006;Troyano *et al.*, 2006;Athanasiou *et al.*, 2007;Orno *et al.*, 2008;Toozs-Hobson *et al.*, 2008). The structures of the perineum can be visualized using linear or circular transducers, and in 2D or 3D ultrasound, however only a few reliability studies have been described to date.

3D TV ultrasound has been described as an accurate and reproducible method of assessing urethral sphincter volume in women (Toozs-Hobson *et al.*, 2001). This method of evaluation has indicated that the urethral sphincter in women with SUI is shorter and thinner with smaller volumes (Athanasiou *et al.*, 1999) is smaller after delivery compared to the third trimester, irrespective of mode of delivery (Toozs-Hobson *et al.*, 2008) and can predict the outcome of continence surgery (Digesu *et al.*, 2009). TR ultrasound has also been used to measure changes in the urethral sphincter volume in patients with bladder outflow obstruction (Noble *et al.*, 1995).

Although 2D TV ultrasound has been used to examine the morphology of the urethral sphincter muscle in women and has been shown to be thinner in women with SUI (Kondo *et al.*, 2001), as the urethra is not a sphere, the volume cannot be calculated reliably from 2D measurements (Toozs-Hobson *et al.*, 2001). The relatively poor agreement between observers evaluating perineal anatomy and extent of perineal tears in 2D imaging implies that both transverse and longitudinal projections are necessary to obtain reliable, relevant information (Orno *et al.*, 2008). However a novel 2D TV technique with good intra-observer and inter-observer reliability using a scanning angle of 360 degrees in a plane perpendicular to the axis of the probe, enabled measurement of the levator hiatal area similar to those obtained by pelvic floor MRI (Athanasiou *et al.*, 2007). Intraclass correlation coefficient (ICC) ranged from 0.62 to 0.99 with confidence intervals (CI) for intra-observer and inter-observer reliability better for hiatal area (0.976–0.998 and 0.932–0.996 respectively) than muscles thickness (0.377–0.915 and 0.025–0.899 respectively) suggesting that morphology and hiatal area can be reliably imaged using 2D ultrasound.

Intra-operative TV ultrasound was shown to standardise Burch colposuspension and helped avoid overelevation and associated post-operative complications such as voiding difficulties and de novo urge incontinence (Viereck *et al.*, 2005). Although no correlation has been found between placement of the sling and postoperative voiding troubles (DeTayrac R. *et al.*, 2006), TV ultrasound has also evaluated post-operative sling position after surgical treatment of SUI (Lo *et al.*, 2004;Schuettoff *et al.*, 2006;Foulot *et al.*, 2007). It has also been shown to be as useful in the evaluation of patients with suspected urethral diverticulum (Gerrard, Jr. *et al.*, 2003) and in a small study of 15 incontinent patients TV ultrasound also correlated 100% with surgical findings in diagnosing vesicovaginal fistula and had greater sensitivity compared to that of more invasive techniques of cystoscopy (93%) and of cystography (60%) (Sohail & Siddiqui, 2005).TV assessment of mean bladder wall thickness has also been shown to be a sensitive screening tool to detect detrusor instability in those women with equivocal laboratory urodynamics (Robinson *et al.*, 2002).

TV ultrasound can also be used to measure displacement of the pelvic organs during manoeuvres in much the same way as TP imaging. However it has been suggested that there is greater distortion of PF anatomy compared to external transducer imagining techniques (Wise *et al.*, 1992;Beco *et al.*, 1994). Subsequently when measuring urethral angles at rest and displacement angles on Valsalva, the pressure of the tip of the transvaginal probe artificially widens the urethral angle and it is suggested that it is not a reliable measurement tool (Alper *et al.*, 2001;Beco *et al.*, 1994). Furthermore insertion of any device within the pelvic floor will produce greater stiffness of the PF, and may reduce the total amount of displacement during manoeuvres.

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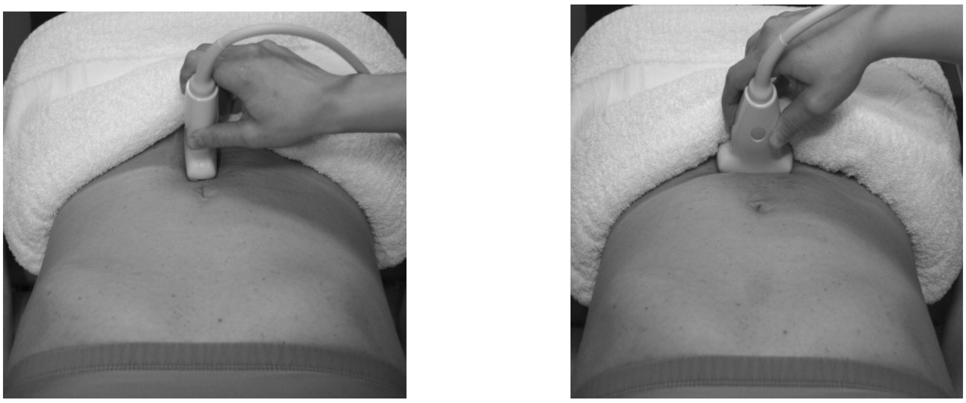
2.3.4 2D Transabdominal (TA) imaging

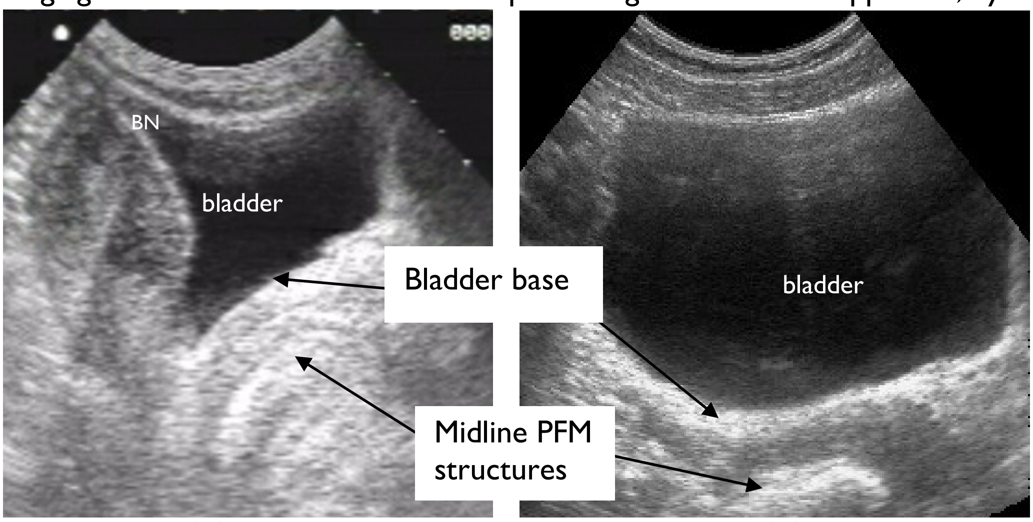
TA ultrasound imaging of the bladder was initially described in 1980 for the evaluation of urinary stress incontinence (White *et al.*, 1980), however has been more recently used by physiotherapists to measure the displacement of the bladder base during a voluntary PFM contraction, Valsalva and functional tasks (Thompson & O'Sullivan, 2003;Sherburn *et al.*, 2005;Bower *et al.*, 2006;Thompson *et al.*, 2006b;Whittaker *et al.*, 2007b;Frawley *et al.*, 2006a;Frawley *et al.*, 2006c).

2.3.4.1 Technique and current measurement methods: TA imaging places the ultrasound transducer suprapubically in a sagittal or transverse direction, viewing the bladder and levator plate on which it rests (Figure 2.6, 2.7).



(a) *(b)*

Figure 2.6: TA Ultrasound transducer placement for (a) sagittal and (b) transverse ultrasound imaging of the bladder. Reproduced with permission from Elsevier Ultrasound Imaging for Rehabilitation of the Lumbopelvic Region: A Clinical Approach, by Whittaker



(a) *(b)*

Figure 2.7: Typical (a) sagittal (b) transverse plane TA view of the bladder, bladder base (BB) and midline PF structures.

As there is no fixed structure, such as a bony marker to take a reference point, a defined point, typically at the point of greatest observed displacement is selected for measurement. The position of this point at rest is marked by the operator electronically and then again at the end of a manoeuvre. The displacement to its end position is then calculated with electronic callipers (O'Sullivan *et al.*, 2002;Thompson & O'Sullivan, 2003;Sherburn *et al.*, 2005). Unlike the sagittal plane image, the transverse plane image also provides the possibility to view asymmetry of elevation of the bladder base during a PFM contraction (Jones *et al.*, 2006;Whittaker *et al.*, 2007b). Whether this observation corresponds to a clinically significant result such as asymmetry of PFM contraction or deficiency in fascial attachment is yet to be established under researched conditions.

2.3.4.2 Reliability and specificity: Good intra-observer and inter-observer reliability for sagittal and transverse bladder base displacement has been reported during a PFM contraction (ICC, 0.81-0.88) (Sherburn *et al.*, 2005). Good intra-observer reliability of transverse view TA imaging has also been reported during an active straight leg raise (ICC 0.98) (O'Sullivan *et al.*, 2002), however only moderate reliability for the sagittal TA view measurement of a Valsalva manoeuvre (ICC 0.51) and trunk curl (ICC 0.53) (Thompson *et al.*, 2005;Thompson *et al.*, 2006b). No studies to date have evaluated the specificity or sensitivity of TA imaging to detect SUI or prolapse, however paravaginal defects in women with SUI, confirmed in surgery, did correspond with defects identified with transabdominal ultrasound (Ostrzenski & Osborne, 1998;Martan *et al.*, 2002)

During voluntary PFM contraction, Valsalva and abdominal curl manoeuvres, there were no significant differences in displacement values using TA measurement between 60 continent and 60 incontinent women (Thompson *et al.*, 2007). In comparison, TP measurements of the same group and manoeuvres were able to detect significant differences between groups during a Valsalva and abdominal curl ($P < 0.004$) and a strong trend for the continent women to have greater elevation ($p=0.051$) during a voluntary PFM contraction (Thompson *et al.*, 2007).

2.3.4.3 Validity and correlation with other methods of PFM assessment: As indicated in the study above comparing TA with TP imaging (Thompson *et al.*, 2007); there are difficulties in imaging techniques where apparent motion of the bladder base caused by movement of the transducer is not accounted for due to the absence of a fixed reference point. In their earlier studies, a divergence in bladder base (observed with

TA imaging) and bladder neck motion (observed with TP imaging) was observed in 15% of subjects (Thompson *et al.*, 2005;Thompson *et al.*, 2006b). The bladder base in TA imaging can be interpreted as descending, when in fact; it may be caused by an increase in distance from the transducer to the bladder base caused by abdominal muscle activity and/or increases in intra-abdominal pressure pushing the transducer out. As discussed earlier, in TP ultrasound imaging, not accounting for apparent motion of the transducer results in significant measurement error (Reddy *et al.*, 2001).

Digital strength grading does not correlate with TA ultrasound measures in either transverse or sagittal planes (r = 0.21 and -0.13) (Sherburn *et al.*, 2005), therefore diligence and due care is required to interpret the "lifting" aspect of the PF as a measure of strength of PFM contraction. To highlight this common error of interpretation; a recent study, without assessing vaginal digital palpation or accounting for the initial starting position of the PF, concluded that adults were more able to contract their PF in standing than in supine, based on the greater degree of lift observed in the standing compared to supine position (Kelly *et al.*, 2007). An earlier study utilising TA ultrasound views had indicated that although there was greater lift observed in standing, digital muscle testing and vaginal squeeze-pressure scores were highest in the lying position (Frawley *et al.*, 2006a).

TA imaging is particularly suitable for certain populations such as children and adolescents as the patient need not undress. In addition, as the PFM have also been implicated in sacro-iliac, low back and pelvic pain, (Lukban *et al.*, 2001;Pool-Goudzwaard *et al.*, 2004;Hodges *et al.*, 2007), judicious use and interpretation of TA ultrasound images may provide, in the future, a useful initial screening or biofeedback tool of a PFM contraction.

However, interpretation of the amount of bladder elevation or depression in TA and TP imagining is complicated by pre-existing PFM activity and laxity of the myofascial system. If the PFM are already activated or there is little laxity of the myofascial system, such as in children or nulliparous women, further elevation of the bladder base may not occur during a voluntary PFM contraction. Conversely, bigger displacements may occur when there is more significant fascial laxity, as the bladder base may start in a more caudal position. In addition, increasing thickness of the PFM may not provide appropriate support to the urethra of PF if there is a tear in the endopelvic fascia.

2.4 The need for future research

Although there seems a plethora of instruments to evaluate the voluntary activation of the PFM, it seems appropriate to discover whether other properties of muscle function, such as timing of a PFM contraction and its influence on other structures, particularly during dynamic events are also important in defining PFM function and dysfunction. This could create greater understanding of how PFM dysfunction exists in SUI and other conditions such as, for example, prolapse, urgency incontinence, back and pelvic pain. In addition, the critical components of effective rehabilitation in women with PF dysfunction could be determined.

One well known PF research group has utilised current TP ultrasound approaches extensively and acknowledge the limitations of the existing methods (Lewicky-Gaupp *et al.*, 2009). To date, ultrasound studies have measured the re-positioning of urogenital structures from the start to the end of the manoeuvre, which may be of limited value because intermediary anatomical changes are not registered. They state that as the current methods can only focus on the movement of a single point, they lose the complex movement patterns of the PF viscera that occur, particularly during rises of intra-abdominal pressure (IAP). They particularly hoped to be able to identify specific patterns of urethral movement during a cough so that future objective evaluation techniques could then analyze these identified patterns. Unfortunately, they concluded that to date, with existing methodologies, experts could not identify patterns of movement characteristic of SUI on ultrasound.

Although more definitive identification of the mechanisms involved in PF dysfunction could potentially be made using 3D ultrasound imaging, the current frame rates obtained with 3D imaging are too slow to capture sufficient images during dynamic events such as a cough. Furthermore, as 3D imaging is cost prohibitive for the majority of clinicians it is anticipated that 2D ultrasound will be, for the foreseeable future, the measuring and feedback tool of clinical choice. Recent advances in 2D ultrasound utilising a 360 degree intravaginal probe allows excellent visualisation of the levator hiatus, comparable to 3D ultrasound (Athanasiou *et al.*, 2007). This 2D technique could potentially be utilised in the future if the frame rate is fast enough and the intravaginal probe is shown not to affect the displacement of the PF structures, particularly during automatic events such as coughing.

2.5 Summary

The study of the biomechanics of the pelvic floor and urethra during dynamic events typically triggering SUI has been neglected in the past due to the limitations of appropriate instrumentation. Muscle strength, EMG studies or imaging techniques considered alone do not provide compelling evidence that can be reliably used to identify the physiological processes maintaining continence and many questions relating to the function of the PFM remain. A major contributing factor for this has been the lack of dynamic and quantifiable measures to enable the comparative characterization of PFM function between normal and incontinent subjects. The focus of existing instrumentation and conservative rehabilitation to date, particularly within SUI, has been upon strength and endurance of the PFM. Only latterly has timing of PFM contraction and interaction with other muscles of the lumbo-pelvic cylinder been considered in PFM rehabilitation. It is therefore unclear whether conservative or surgical care for SUI or other PFM dysfunctions could become more effective if other properties of PFM function, such as timing, co-ordination with other muscle groups, and direction of PFM contraction are also considered. Indeed, as more properties of efficient PFM and urethral function are defined, not only will this lead to a better understanding; specific classification of dysfunction could be used to select patients for the most appropriate treatment, whether conservative rehabilitation or appropriate surgical care.

The aim of this current study is therefore to define new quantitative parameters of PFM function using 2D perineal ultrasound imaging combined with image processing methods, to enable the dynamic evaluation of PF displacement throughout an entire manoeuvre, rather than limiting the quantification from static images at rest to the end of the manoeuvre.

2.6 Research outline and structure

This current chapter has discussed the rationale behind the current research which aims to define new quantitative parameters of PFM function, particularly during automatic events. It has described the basic principles of ultrasound imaging and discussed the benefits and limitations of current 2D ultrasound imaging methods. Chapter 3 describes the general methodology for acquiring the data, the subjects, equipment, testing procedures, protocols and general limitations. Chapter 4 describes the pilot studies that were used to test the viability of two image processing methods (IPM); speckle tracking and segmentation, on the captured audio- visual image (AVI) ultrasound files. The mathematical algorithms and methodology developed to process the ultrasound images are described in detail and were developed in collaboration with Dr Qiyu Peng PhD and Dr Christos Constantinou PhD at Stanford University, California, USA. This chapter begins to describe the preliminary findings of the data analysis and provides some indications of PFM function during dynamic events not previously described. Chapter 5 describes the intra and inter-observer reliability of both IPM, providing suggestions for future studies, to improve the reliability of the measurement tool. It describes which IPM were chosen, and why, to evaluate the rest of the collected ultrasound data. It concludes by discussing the limitations of the study as a whole, and the rest of the thesis should be read with these limitations in mind. Chapter 6 describes the effect of a cough on the PF and is the first of six clinically orientated chapters which detail the effect on the Ano-rectal Angle (ARA) and urethra of each of the test manoeuvres utilised in the investigation. Chapter 7 describes methods and determines the reliability for assessing the effect of posture on the PF, calculating the strain on the PF during a cough in both supine and standing. Chapter 8 describes the effect of a PFM contraction held prior and throughout a cough, "The Knack" and explains why this commonly used technique in conservative rehabilitation of SUI may or may not be successful. Chapter 9 reports the inter-observer reliability of vaginal palpation, and introduces a new digital measurement scale of PFM function devised by the author, "The Functional Scale" which attempts to determine, without the availability of ultrasound, the ability of the PFM to provide external support of the urethra during a cough. Chapter 10 calculates the displacement values of the ano-rectal angle (ARA) and urethra during a PFM contraction in supine and standing and illustrates the caution required when interpreting large displacements on ultrasound without accounting for the relative starting position. The validity of the Functional Scale and 2D TP ultrasound and IPM is evaluated in Chapter 11. Chapter 12 describes the preliminary investigation of a novel vaginal pressure probe designed to enable the specific localisation and measurement of the pressure changes that occur in the vagina during a PFM contraction. Chapter 13 describes the effect of a Valsalva (forced expiration technique) on the PF and urethra, in addition to comparing the amount of urethral displacement during a Valsalva to displacement values of a cough previously described in Chapter 6. Chapter 14 looks at the effect that an abdominal manoeuvre, commonly used in rehabilitation of low back and sacral pain, has on the PFM and urethra, providing some important guidelines for clinical use. Chapter 15 describes the main impacts of this current research and discusses the study population and design of the research including the qualities and limitations of 2D TP ultrasound combined with IPM. It relates each of the experimental chapters to one another and to other published literature, in order to propose a model of optimum PFM function as well as presenting ideas for future research. The final chapter lists the main conclusions of the research.

The next chapter describes the general methodology of the current study which aims to define new quantitative parameters of dynamic PFM function using 2D perineal ultrasound imaging combined with image processing methods, and a novel intra-vaginal probe.

3 General Methodology and Equipment

3.1 Introduction

This chapter describes the methodology used in this investigation and outlines how the data was acquired; the volunteers and their general demographic; the examiners, their experience, profession and various roles within the study. This is followed by the description and respective justifications of the equipment and methodology used.

3.2 Ethical approval:

The Institutional Review Board (IRB) of Stanford University approved the experimental protocol used. All women had a mailed narrative of the principals of Pelvic Floor Muscle (PFM) function and were given an oral description of the methodology to be followed. Witnessed written informed consent was obtained from all subjects prior to the commencement of the investigation. The project was funded in part by NIH-NIBIB Grant #1 R21 EB0016.

3.3 Volunteers:

A convenience sample of thirty six (36) female volunteers was recruited according to a protocol approved by the Stanford University IRB committee from the general community of San Francisco Bay Area. Women were recruited through networking and fliers posted at schools, hospital, sports associations and Stanford University. They completed a demographic questionnaire, a validated short form Incontinence Impact Questionnaire (IIQ-7) and short form Urogenital Distress Inventory (UDI-6) (see Appendix 5).

The investigators were blinded to the continence status of the volunteers, who after evaluation, were divided on the basis of history and self reported symptoms to asymptomatic: no reported incontinence; and to those with Stress Urinary Incontinence (SUI) with their continence severity defined by a 12 point scale (Sandvik *et al.*, 2000). Exclusion criteria were women who had previous genitourinary surgery; described symptoms associated with overactive bladder (OAB) or were currently using pharmacotherapy for OAB; were currently pregnant; had a neurological or psychiatric disease, major medical condition, significant prolapse, urinary tract or vaginal infection. One volunteer was excluded due to symptoms of Overactive Bladder (OAB).

Due to the unavailability of an ultrasound machine at the commencement of the investigation, and the exclusion of the volunteer with OAB, thirty two (32) women were available for 2D ultrasound evaluation. These thirty two women are the only volunteers of interest in all experimental chapters except for Chapter 12 which discusses a novel intra-vaginal pressure probe, and the digital vaginal examination in Chapter 9. Further information regarding the additional three (3) volunteers will be described later in the relevant chapters.

The general demographic of the two groups available for ultrasound evaluation is described below (Table 3.1). The severity scale by Sandvick et al (2000), determined five of the incontinent group to be slightly incontinent; which equates to a few drops of urine a maximum of a few times a month; and four moderately incontinent, a few drops or splashes of urine a maximum of a few times a week. There was no subject that rated severely incontinent. Overall, the bothersomeness of the condition was slight, determined by analysis of the UDI-6 and IIQ-7. Five subjects indicated that they were slightly bothered, three were moderately bothered and one was greatly bothered by their incontinence.

Table 3.1: Mean+/- Standard Deviation (SD) and range of Age and Parity, Body Mass Index (BMI), and Continence Severity Scale (CSS)

	Continent (N = 23)	**SUI (N = 9)**	**P Value**
Age	40.8 ± 13.8 (25 to 84)	46.8 ± 12.9 (34 to 71)	NS P = 0.24
Parity	0.5 ± 0.9 (0 to 3)	1.4 ± 0.8 (0 to 2)	**P = 0.01**
BMI	22.0 ± 2.0	23.9 ± 2.6	NS P = 0.09
CSS	Continent	5 Slightly 4 Moderately	

Although the study was primarily a proof of concept and feasibility study to investigate mechanisms and define new quantitative parameters of PFM function; 80-95% power calculations for this unequal sample size, based on a SD of urethral displacement of 0.5cm during a cough (Howard *et al.*, 2000), suggested that this sample size was large enough to avoid type II statistical errors, and therefore reasonable to compare groups for significant differences (Lenth, 2006).

There was a significant difference in parity between groups and epidemiological evidence suggests correlation between parity status and incontinence (Foldspang *et al.*, 1992;Rortveit *et al.*, 2001;Viktrup *et al.*, 2006). Yet sister pair and identical twin studies have also reported that vaginal delivery is not associated with urinary incontinence, concluding that underlying familial predisposition toward the development of urinary incontinence may be present (Buchsbaum *et al.*, 2005;Buchsbaum & Duecy, 2008).

It was beyond the scope of the current study to look at the effect of parity on either sample group, so caution regarding the generalisability of the results from the experimental chapters found later in the thesis is warranted, however they may provide the foundation for future studies with larger and parity matched populations.

3.4 Investigators:

RLJ was a physiotherapist with 20 years of clinical and lecturing experience and 12 years more specifically working within women's health, particularly associated with education, motor control and manual therapy. RLJ had over 7 years of clinical and educational experience using perineal and transabdominal ultrasound but prior to these experiments, no image processing experience. RLJ designed the study protocols, physically examined the volunteers, including acquiring the ultrasound and intra-vaginal probe measurements. QP was an engineer and developed the software programmes for the ultrasound and intra-vaginal probe. Prior to these experiments, he had 6 months experience of observing urology ultrasound scans and 5 years of doctoral and post doctoral research in ultrasound imaging and image processing methods.

CP was an uro-gynaecologist with over 15 years experience as a specialist in Female Urology and Incontinence and Pelvic Reconstructive Surgery. He performed the reliability testing for the digital vaginal examination. CC was the principal investigator and a biomedical engineer who, in collaboration with colleagues from Japan University, designed the intra-vaginal probe. He had almost 40 years of experience of research in urology.

3.5 Equipment and Method of Application:

3.5.1 2D Dynamic ultrasound: A commercially available ultrasound scanner (Hitachi EUB- 52) with a 3.5-5 MHz high definition curved linear array transducer with a footprint of 10cm was used throughout the study (Figure. 3.1). The size of the ultrasound image was 320x240 pixels at 8-bit resolution at a rate of 30 frames per second. Analysis of video data was performed using a 2 CPU HP workstation using MATLAB 7.1 software.

3.5.2 Transperineal Ultrasound (TP): To satisfy local infection control procedures, the transducer was washed in hot water and disinfectant, covered in ultrasound gel, then covered by an un-powdered examination glove followed by more ultrasound gel before being placed on the perineum in a mid sagittal direction, orientating the transducer so that the clearest images of the bladder, urethra, rectum and symphysis pubis (SP) were viewed (Figures 2.12).

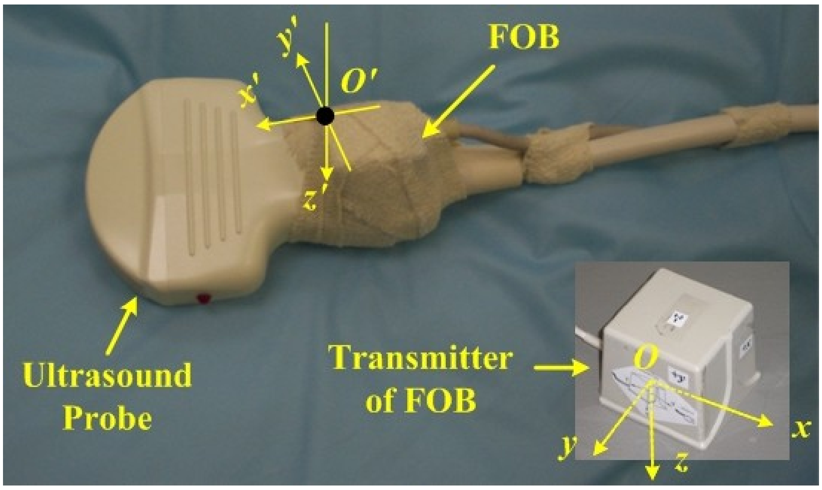


Figure 3.1: The ultrasound transducer fixed with a 3D positional sensor, the Flock of Birds.

The exact position of the transducer on the perineum was dependent on the ultrasound image viewed and was applied with sufficient skin pressure to maintain the location and orientation of the urogenital structures, without distorting the pelvic structures (Schaer *et al.*, 1996). Transperineal rather than trans-vaginal or rectal ultrasound was chosen for the study due to the desire to minimise any distortion, or increase the stiffness of the PF during manoeuvres.

3.5.3 Transabdominal Ultrasound: To view transversus abdominis (TrA) and the oblique abdominal muscles the transducer was placed transversely across the abdominal wall along a line approximately midway between the inferior angle of the rib cage and the iliac crest. The medial edge of the transducer was adjusted to ensure that the medial edge of TrA was viewed approximately 2cm from the medial edge of the ultrasound image when the subject was relaxed (Figure 3.2) (Rankin *et al.*, 2006;Springer *et al.*, 2006).

3.5.4 3D Positional Sensor: To keep the out-of-plane rotation of the ultrasound transducer in an acceptable range (< ±5°) and to track the orientation the vaginal probe, a six degrees-of-freedom measuring device a Flock of Birds, (FOB) (Ascension technology Corporation VA, USA) was used fixed on the handle of the ultrasound transducer and vaginal probe (Figure. 3.1, 3.3).

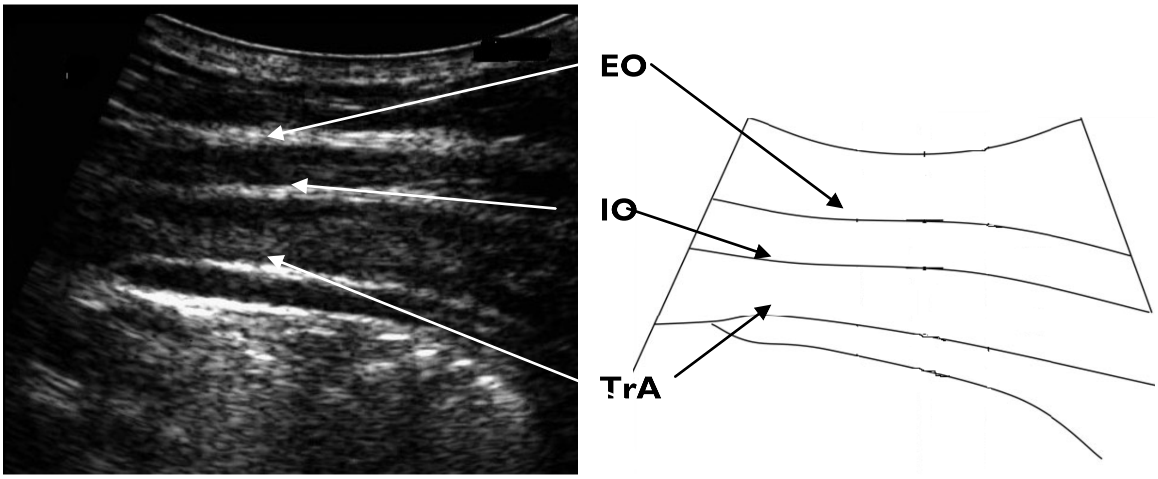


Figure 3.2: Typical ultrasound image of TrA and Oblique Abdominals (External Oblique (EO); Internal Oblique (IO)) and diagrammatical

The FOB can track the position (x, y, z) and orientation (azimuth, elevation and roll angles) of multiple sensors (called birds) by a transmitter. Each bird is capable of making from 20 to 144 measurements per second of its position and orientation when the sensor is located within ± 1.5 metres of its transmitter. The transmitter was sited on the ground about 1m from the bird, and a global coordinate system (*x*-*y*-*z*) was fixed on the transmitter (Figure 3.3). The orientation of the ultrasound transducer was visualized in real-time during scanning and vaginal sensor measurements.

3.5.5 Intra-vaginal pressure sensor: The prototype probe was comprised of an applicator with retractable low inertia cantilevered force and displacement sensors in four directions (anterior, posterior, left and right) (Figure. 3.3, 3.4).

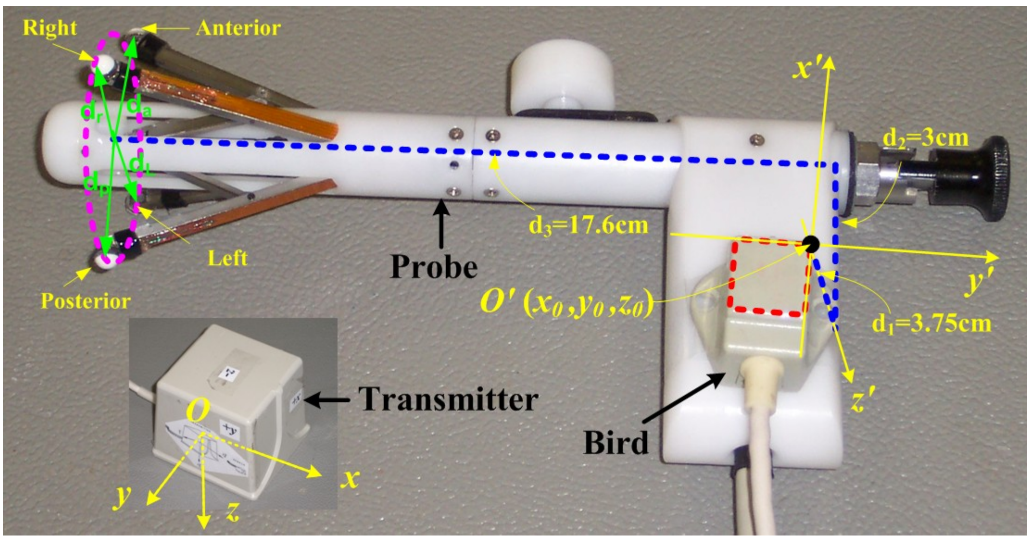


Figure 3.3: The four-channel vaginal palpation probe consists of a probe and 3D positional sensor the Flock of Birds (bird) attached to handle and transmitter sited on ground.

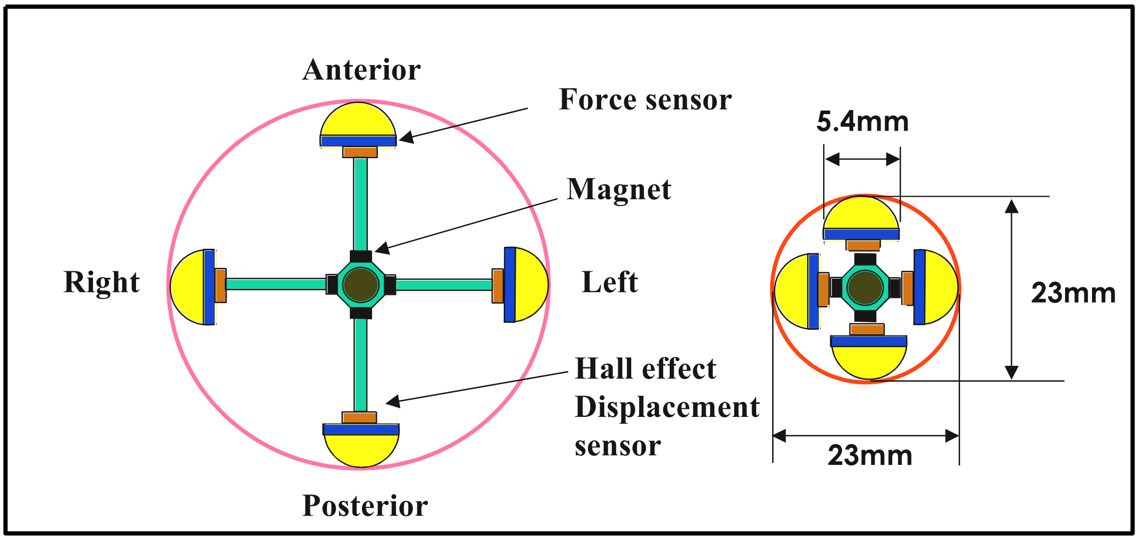


Figure 3.4: Cross section of the probe and four sensors

The technical details of the probe have been reported (Constantinou & Omata, 2007) however further details of the intra-vaginal probe, its merits and limitations are given in Chapter 12 and algorithms for calculations of pressure are given in Appendix 5c.

The force transducers and probe were covered with a female condom turned inside out for extra lubrication and closed until they were inserted into the vagina. Once the probe was fully in place, a diameter adjustor was gradually released to allow opening from its retracted position so that the transducers made contact with the vaginal wall. The length between the four transducers and the bottom of the probe was 8.0cm and the diameter of the sensor site was 23mm for all the subjects because all the sensors had already made contact with the vaginal walls before the diameter adjustor was released. By inserting the device into the vagina, the contact pressures in the anterior, posterior, left and right directions were measured (Figure 3.3, 3.4).

The data were transferred to a personal computer (section 3.5.3) where they were stored and presented graphically on the computer screen. The sample rate of the force and displacement signals was 25Hz.

3.5.6 Personal Computer HP Compaq nx9010:

The 8-bit greyscale ultrasound images were captured using a video to USB capture card and stored in the uncompressed AVI format for image analysis on a personal computer. The ultrasound image size was 320 × 240 pixels with a frame rate of 30 frames per second. The intra-vaginal probe measurements were recorded and transferred to the computer via serial port RS232.

3.5.7 Microphone: Plantronics Audio™ 60 stereo PC headset was placed at the foot of the examination couch on a fixed hook. A microphone was used in order to have an audio back up verifying the manoeuvre being performed by the volunteer captured on the AVI file.

3.6 Protocols

The next section describes the general format of the examination procedure, but specific details regarding positioning, elicitation and verification of the manoeuvres may be found in the later named chapters.

3.6.1 General Instructions to Volunteers: To ensure adequate bladder volume for ultrasound imaging, a standardised pragmatic approach was taken; the volunteers were asked to void 1 hour before testing, then drink 16floz (450mls) of water and to refrain from voiding until after the test sequences.

3.6.2 Testing Procedures: The testing sequences and order of probe and ultrasound examination protocols were randomly reversed, however to minimise any bias by the examiner (RLJ) observing the ultrasound screen, the vaginal examination was always performed by RLJ prior to the collection of ultrasound and probe data. Details regarding the various digital palpation methods and reliability testing are found in Chapters 9.

With the ultrasound transducer or vaginal probe in place, the volunteers were asked to perform five manoeuvres:

a. Cough (Chapter 6 and 7)
b. A voluntary PFM contraction held before and during a cough: "The Knack" (Chapter 8)
c. Voluntary PFM contraction (Chapter 10)
d. Valsalva (Chapter 13)
e. Voluntary abdominal drawing in manoeuvre that elicited a TrA contraction (Chapter 14)

All manoeuvres were repeated three times and the mean measure was used in the subsequent data analysis.

3.7 Summary

This chapter has described the general methodology and equipment used in this thesis designed to assess the feasibility of image processing techniques to analyse perineal ultrasound images, and a multi-directional intra-vaginal probe to define new quantitative parameters and investigate mechanisms of PFM function. The next chapter discusses two image processing methods used to extract data from the ultrasound images acquired from the sample population.

4 Image Processing Methodology

4.1 Introduction

As described in Chapter 2 Section 2.9, although there are a number of instruments evaluating the voluntary activation of the pelvic floor muscles (PFM), there is a scarcity of instruments able to evaluate the PFM during dynamic events. Indeed even dynamic ultrasound evaluation thus far has been limited to observations and measurement at rest, and then again at the end of the manoeuvre. Techniques that could capture the whole movement patterns of the pelvic floor (PF), particularly during functional manoeuvres likely to provoke incontinence, could provide important information defining the optimum function of the PFM and urethra. This chapter describes the pilot studies of two different image processing methodologies applied to the transperineal (TP) ultrasound images and the rationale behind the use of each one. Qualification and interpretation of the results, including differences between groups and postures will be discussed in the specific experimental chapters, after the reliability analysis in Chapter 5.

4.2 Aims

To investigate the feasibility of two different image processing methodologies; “speckle tracking” and “segmentation” to capture, visualize and quantify the sequence of dynamic changes on the pelvic floor captured during transperineal (TP) 2D ultrasound imaging.

4.3 Pilot study 1: Speckle tracking

4.3.1 Methods:

Valid ultrasound data of 23 continent women and nine stress urinary incontinence (SUI) women were acquired and recorded as described in Chapter 2. Volunteers were tested in supine crook lying, with one pillow under their head and asked to do a perceived maximum cough three times with a 5 second rest between each.

As discussed earlier in Section 2.10.6, speckle tracking searches for a predefined region of speckle pattern within one frame of the ultrasound image then searches for a similar speckle pattern in the next frame and so on. Speckle tracking requires that the structures being traced do not deform so much that the image processing software is unable to follow their movement. Particularly during dynamic, fast events, such as coughing, the urethra has considerable deformation over a short period, and therefore was unsuitable for analysis using speckle tracking.

As discussed in the literature review Section 2.11.2; in order to accurately map the trajectory of any of the structures of the pelvic floor (PF) during a manoeuvre, any apparent motion created by movement of the transducer during the technique, needs to be tracked and subtracted from the displacements of the tissues being measured. The symphysis pubis (SP) is an ideal rigid landmark to establish a stable coordinate system in TP ultrasound in order to account for movement of the transducer, relative to the structures being examined. An orthogonal coordinate system fixed on the SP, parallel and vertical to the urethra at rest was therefore established (Figure 4.1). When the subject deforms the pelvic floor (State 2 in Figure 4.1), the coordinate system maintains its original position and the ensuing trajectory of urogenital structures can be measured relative to this fixed axis.

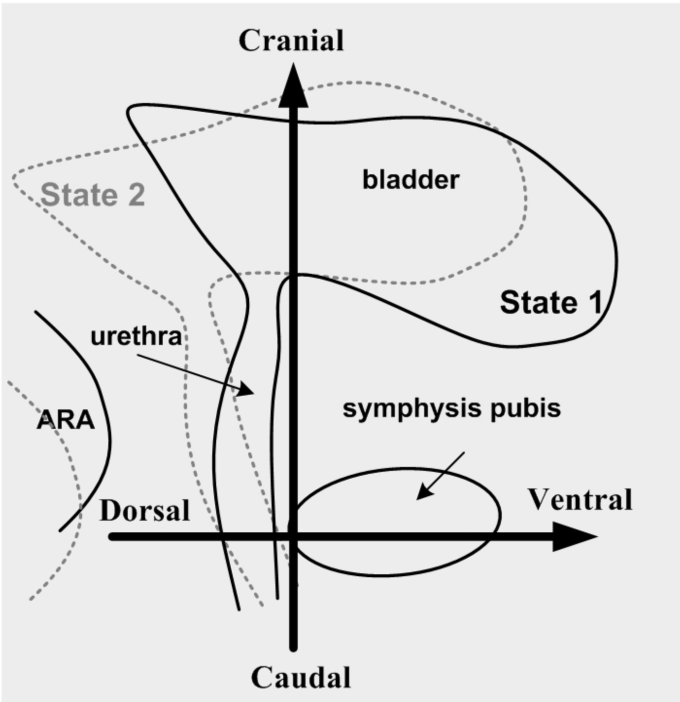


Figure 4.1: The orthogonal coordinate system fixed on the SP. The two orthogonal components (dorso-ventral and caudo-cranial components) of the ARA displacement reflect PFM functions of squeezing the urethra and supporting the bladder respectively.

The angle the rectal ampulla forms with the anal canal, the Ano-rectal angle (ARA) and the SP were tracked using adaptive motion tracking algorithms designed by Dr Qiyu Peng (See Appendix 5a). In order to test whether the algorithm to trace any apparent movement of the SP was reasonable, the movement of the SP measured by ultrasound was compared to the movement of the ultrasound transducer measured by the Flock of Birds (FOB) (see Figure 3.1 and Section 3.5.1) (Appendix 5b).

After the speckle tracking of the SP and ARA, the movement of the ARA was decomposed into dorso-ventral and caudo-cranial orthogonal components. To compare the magnitude and timing of the ARA movement, the displacement signals from different women needed to be synchronized to a same time point in the manoeuvre. For studying the dynamic responses of the PFM to a cough, a reference point that was visible in all volunteers was chosen. This was a point where the ARA had maximum caudal displacement during the cough. This reference point (synchronisation point) is marked by the dashed lines in Figure 4.2 and illustrates the magnitude of displacement in the two directions together with the audio signal used to mark the onset of a cough.

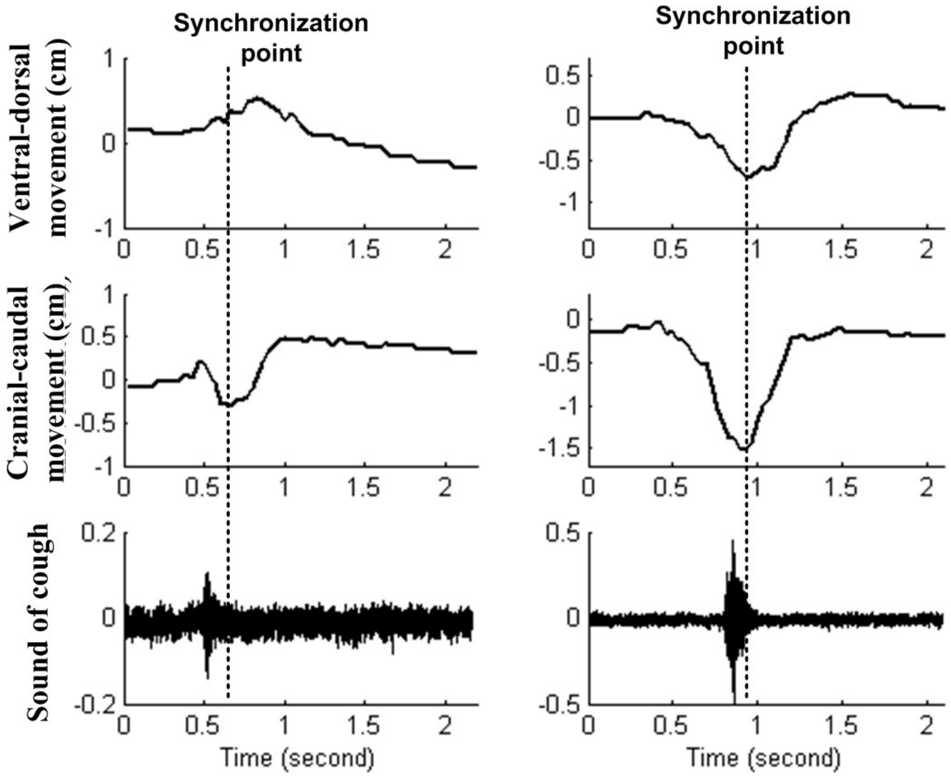


Figure 4.2: Typical dorso-ventral and caudo-cranial displacements of the ARA in one continent and one SUI woman during a cough. The displacements of the ARA are shown relative to the audio recording of the subject's cough. The signals from the continent women and the SUI women are shown in the left and right panels respectively.

Displacement signals derived from each cough episode were differentiated to generate the velocity of displacement, and the second derivative was computed to generate the acceleration values. The resulting values of velocity and acceleration were smoothed using an 8-order Butterworth low-pass filter (cut-off frequency=3Hz) and the filtered velocity and acceleration signals were used to graphically represent the data.

4.3.2 Results:

The movement of the SP measured by ultrasound and the movement of the ultrasound probe measured by the FOB is shown in Figure. 4.3. As the movements of the SP and the ultrasound probe in both x and y direction are similar, it implies that the algorithm to trace the movement of the SP is reasonable.

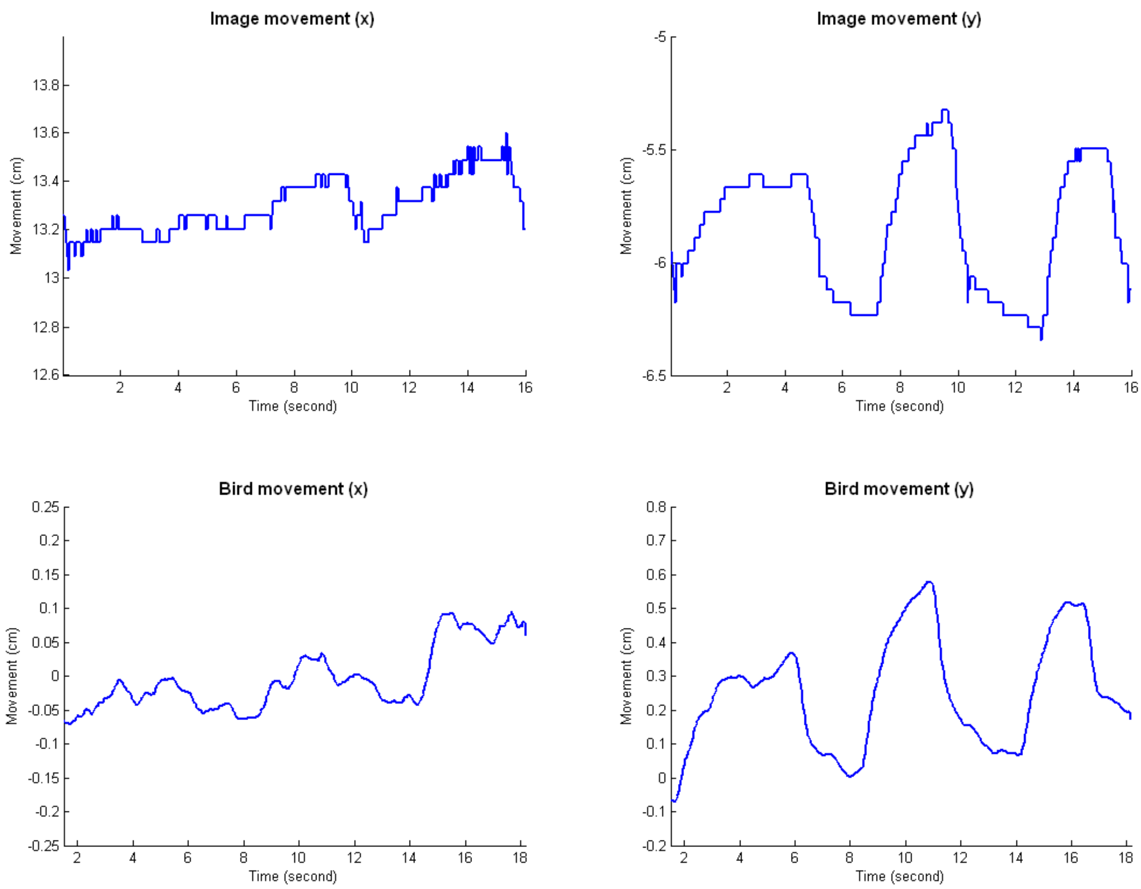


Figure 4.3: Comparison of the movement of pubic bone measured by ultrasound and the movement of the ultrasound probe measured by the FOB.

Typically, speckle tracking takes 15 to 30 minutes to track both the ARA and SP in a 300-frame ultrasound movie, depending on the quality of the ultrasound images. Figure 4.4 illustrates the results of the speckle tracking of a continent woman's SP and ARA in supine. Fig. 4.4 (a) shows the ultrasound image at rest and the cranio-ventral coordinate system. The motion tracking of the SP and ARA are shown in Figure 4.4 (b) and (c) respectively. The relative movement of ARA, shown in Figure 4.4 (d), is derived by subtracting the motion of SP from that of ARA and then transforming the image coordinate system to the cranio-ventral coordinate system.

Speckle tracking was successfully able to track the ARA and SP in both continent and SUI groups. The direction and temporal sequence, velocity and acceleration of the ARA in a cough between the continent and SUI women were further analyzed and are discussed in detail in Chapter 6.

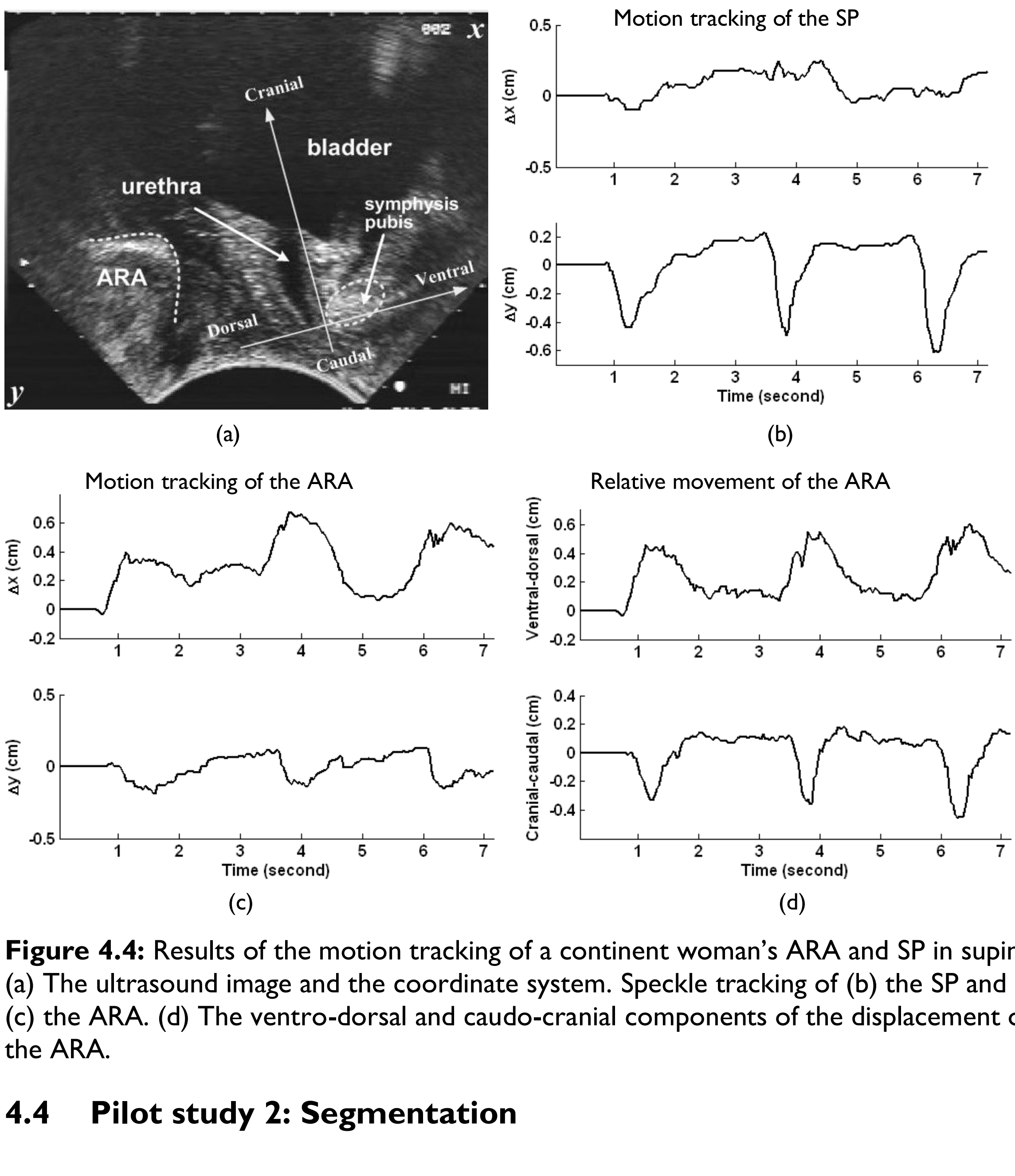


Figure 4.4: Results of the motion tracking of a continent woman's ARA and SP in supine. (a) The ultrasound image and the coordinate system. Speckle tracking of (b) the SP and (c) the ARA. (d) The ventro-dorsal and caudo-cranial components of the displacement of the ARA.

4.4 Pilot study 2: Segmentation

4.4.1 Methods:

As explained earlier, speckle tracking is unable to track the urethra during fast events, such as coughing, as it deforms too much, too quickly. The ultrasound file of one continent woman performing a cough, a PFM and a Valsalva was therefore used as a single pilot study to test the segmentation methodology. A software package of ultrasound image processing based on MATLAB® (Version 7.0 R14) (See Appendix 5c) designed by Dr Qiyu Peng PhD to read and semi automatically process the images from ultrasound movies files one by one following the procedure shown in Figure 4.5.

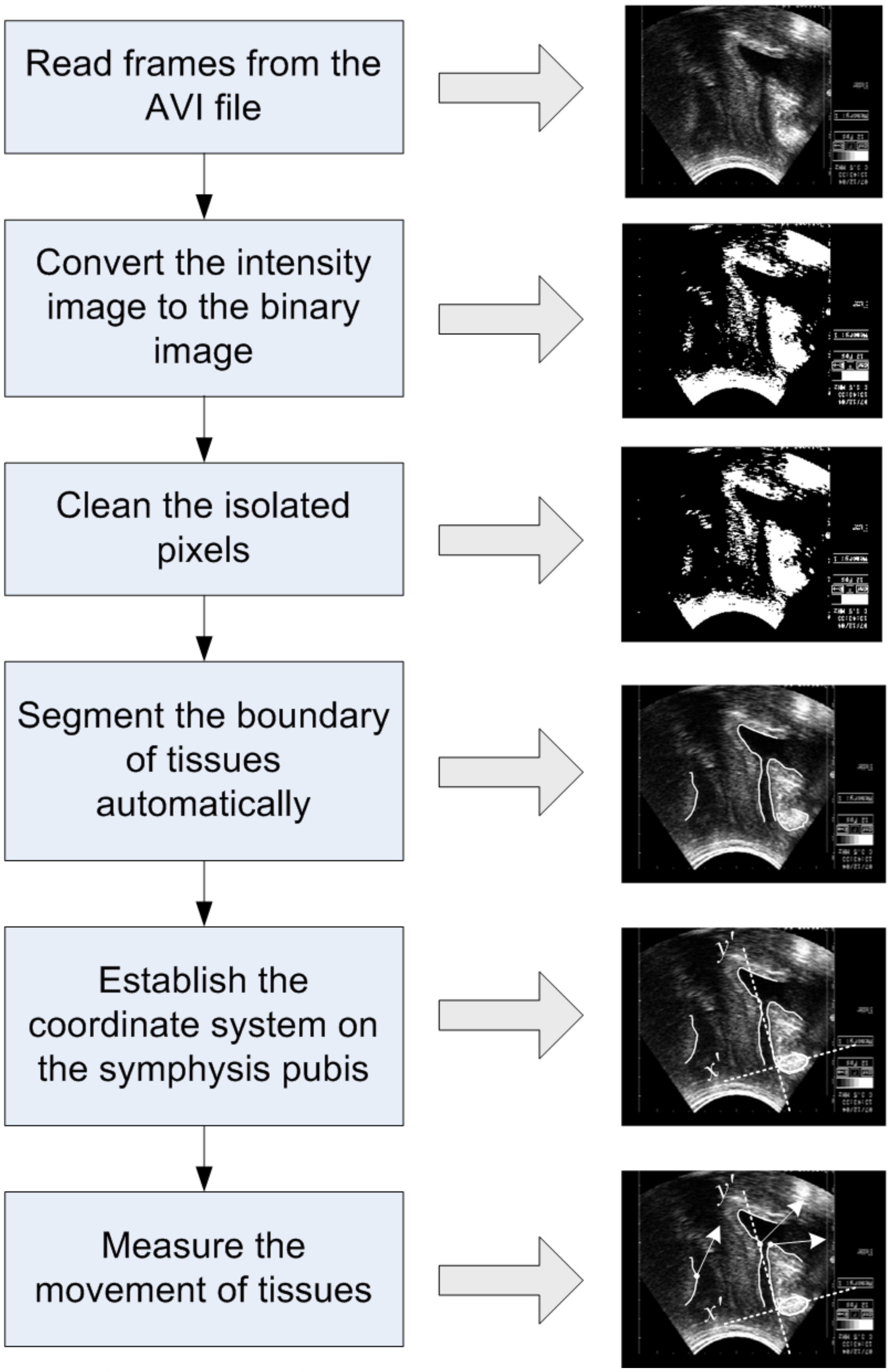


Figure 4.5: Flow chart of segmentation ultrasound images

The boundaries of the anterior and posterior edges of the urethra, ARA and SP were then segmented in the binary images using the automatic segmentation (Figure 4.6).

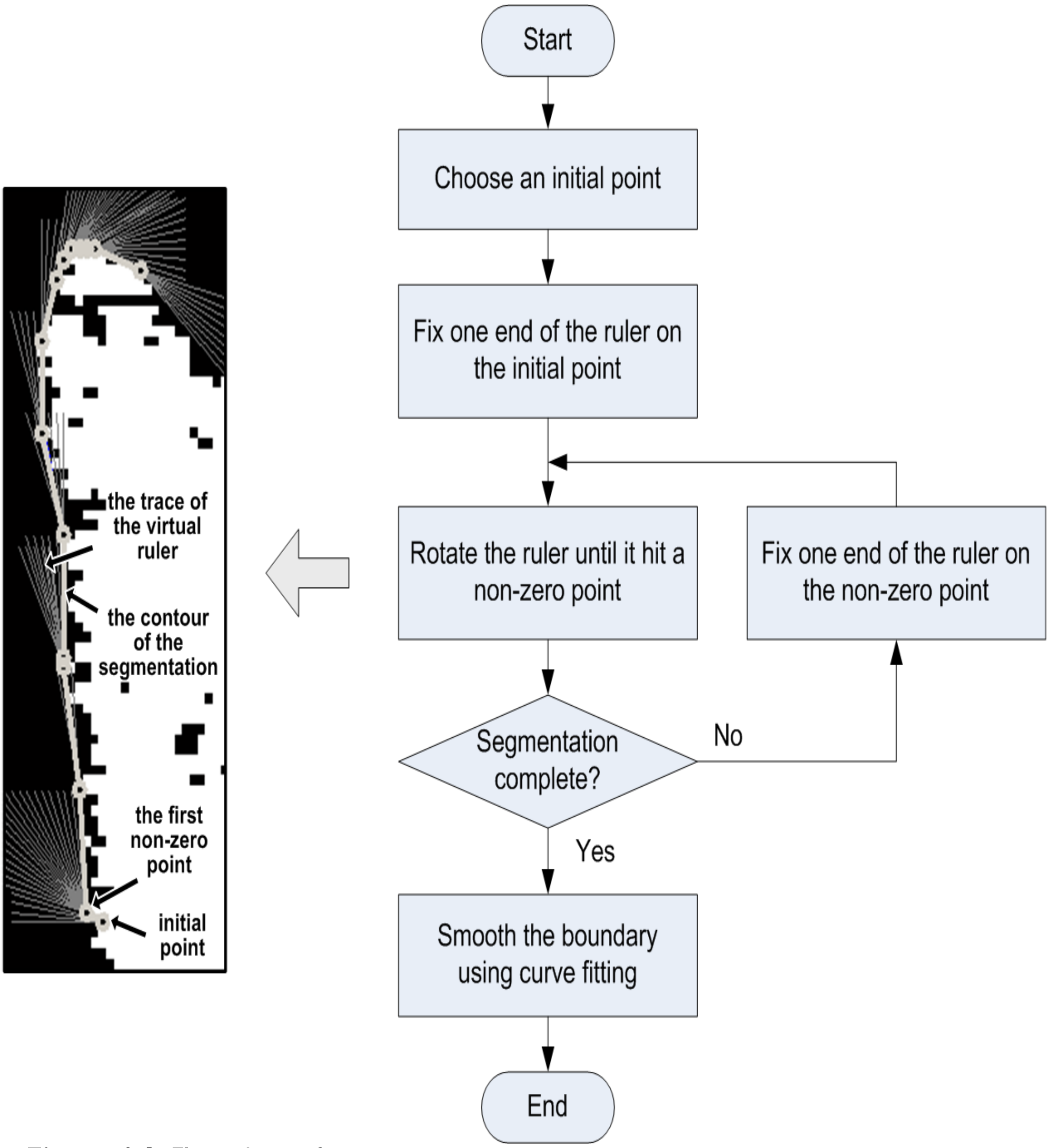


Figure 4.6: Flow chart of automatic image segmentation

An initial point on the edge to be segmented was chosen, and one end of a virtual ruler was fixed on the initial point. The virtual ruler was then rotated around the initial point until it hit a non-zero point on the edge. The fixed end of the virtual ruler was then moved to the non-zero point. The virtual ruler was rotated around the fixed point again until it hit a new non-zero point on the edge. The procedure of moving and rotating the virtual ruler was repeated until the contour of the whole boundary was acquired. The length of the virtual ruler is an adjustable parameter to obtain different resolution of the segmentation. The shorter the virtual ruler, the more detailed information will be elucidated in the segmentation. The results of the segmentation however, will be affected by the noise in the ultrasound images if the virtual ruler is too short. Therefore, the length of the virtual ruler was set from 4 pixels to 16 pixels.

The segmentation algorithm stops when the length of the edge is equal to or greater than the preset value. After the segmentation, smoothing spline, a nonparametric fitting method available in MATLAB® curve-fitting toolbox, was applied to smooth the segmented boundaries of tissues. The smoothing parameter was set to p = 0.8 to obtain the most reasonable results.

After the auto-segmentation of each frame, the software displayed the results and paused for 0.5 second to allow the operator sufficient time to visually check the accuracy of the segmentation. After the segmentations and the smoothing were completed, the results were reviewed to ensure anatomical accuracy.

A coordinate system was then fixed on the posterior inferior margin of the SP (Figure 4.7). The mathematical algorithms used to describe the coordinate system in the segmentation methodology of the SP; ARA and urethra are in Appendix 5c.

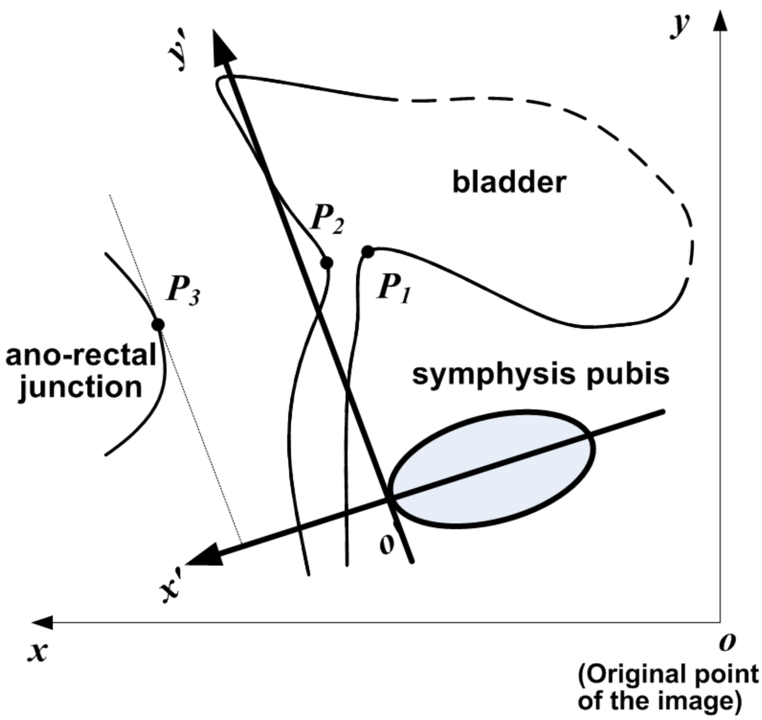


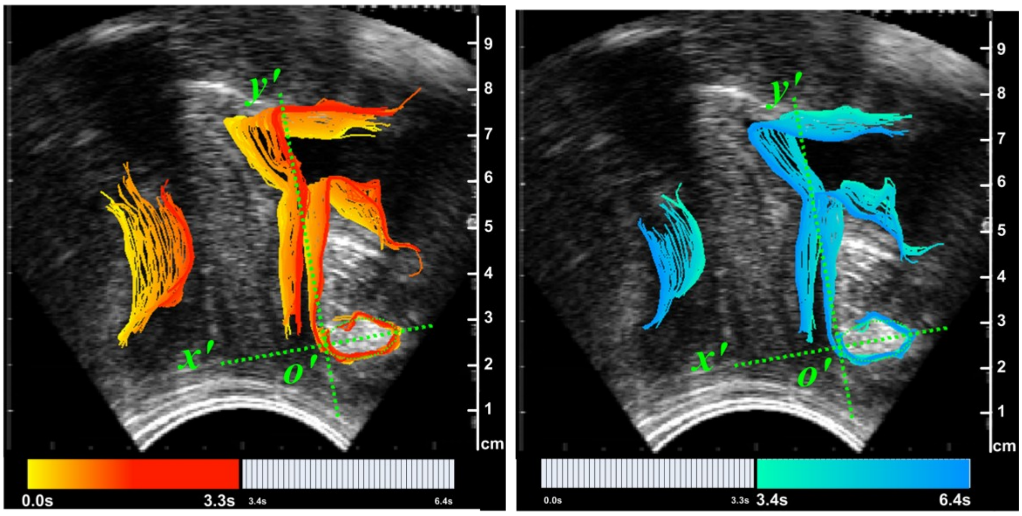
Figure 4.7: Coordinate system of the image (x-o-y) and the coordinate system fixed on the posterior inferior margin of the symphysis pubis (x'-o'-y'). P1, P2 and P3 represent positions on the anterior and posterior edge of the urethra at the urethra-vesical junction (UVJ) and ARA respectively.

Three typical positions (P1, P2 and P3 in Figure 4.7) on the anterior edge and posterior edge of the urethra at the urethra-vesical junction (UVJ) and ARA respectively were then chosen to qualitatively describe the movement of each structure. P3 was the position on the ARA which was the closest to the y' axis. The displacements of the three positions in x' direction and y' direction were measured during a cough, contraction and Valsalva. The change in angle of the posterior edge of the UVJ was also measured. The velocity and acceleration of the movement of three positions in x' direction were then calculated.

4.4.2 Results

Typically, it took about 3-4 hours to segment and quantify the displacement, velocity and acceleration the urethra, ARA and SP in a 300-frame ultrasound movie, depending on the quality of the ultrasound images. Most time was taken to segment and determine the co-ordinate system on the SP; however the method for calculating the moving co-ordinate system was reasonable because the outlines of the static bony landmark were overlapped almost exactly after the process of registration (Figures 4.8-4.10)

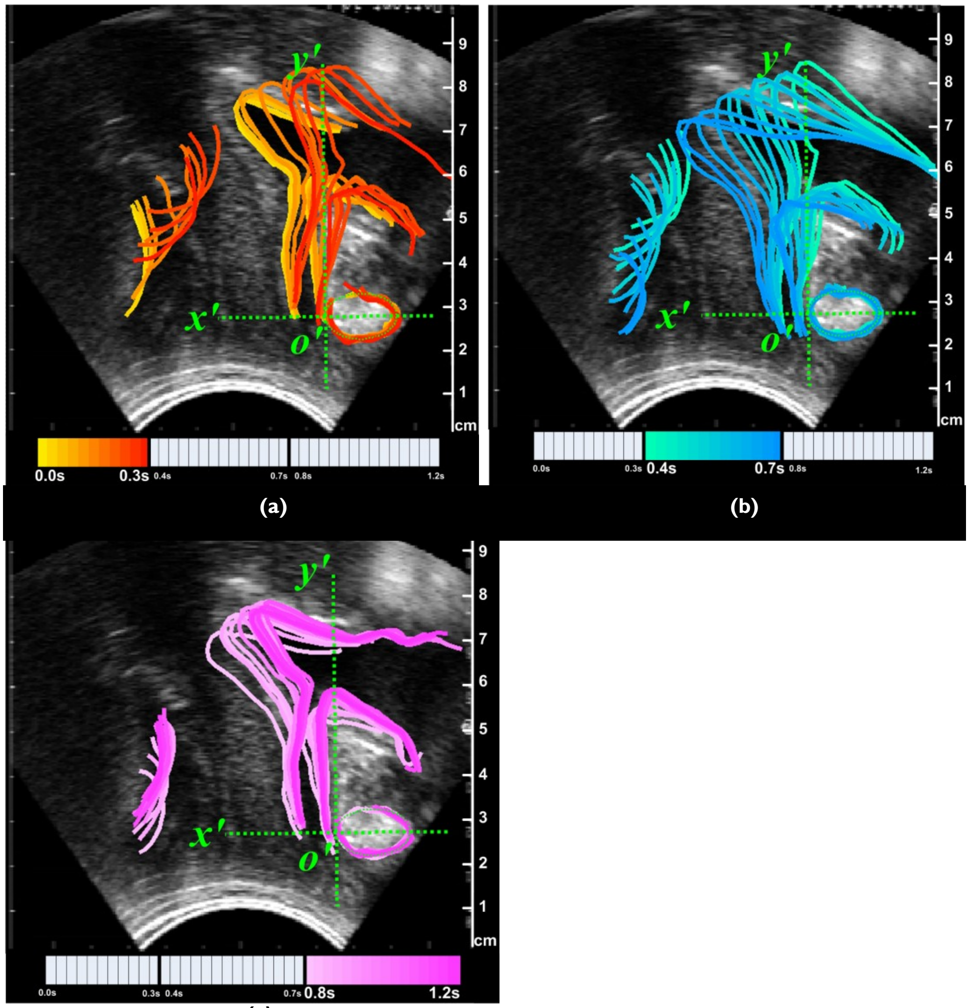
Movement of the edges during a voluntary PFM contraction: During a voluntary PFM contraction, (Figure 4.8a) the ARA and urethra move in a ventro-caudal direction (forward and up). As the contraction is released (Figure 4.8b), the tissues return to the original resting position.



(a) (b)

Figure 4.8: Effect of voluntary PFM contraction showing the movement of the anterior and posterior edges of the UVJ and the ARA during (a) contraction and (b) release.

Movement of the edges during a cough: There were three phases to the displacement of the urogenic structures during a cough in the healthy volunteer (Figure 4.9). During the first 0.3 seconds they moved in a ventro-caudal direction (Figure 4.9a) before moving in a dorso-caudal direction (Figure 4.9b). They then passed beyond the initial resting position (0.4 to 0.7 seconds) before moving from the rightmost position back to the initial resting position (Figure 4.9c) as the volunteer finished the cough (0.8 to 1.2 seconds).



(c)

Figure 4.9: Effects of a cough showing the movements of the anterior and posterior edges of the UVJ and the ARA. The scale is shown on the right side of each image. The timing of the movement is shown in curves with different colours. The coordinate system, fixed on the posterior inferior margin of the symphysis pubis (x'-o'-y'), is shown by the dotted green lines.

Movement of the edges during a Valsalva: As the volunteer performs this forced expiration technique, the PF structures move from their resting position in a dorso-caudal direction (Figure 4.10a) before returning to their resting position as the volunteer completes the manoeuvre (Figure 4.10b)

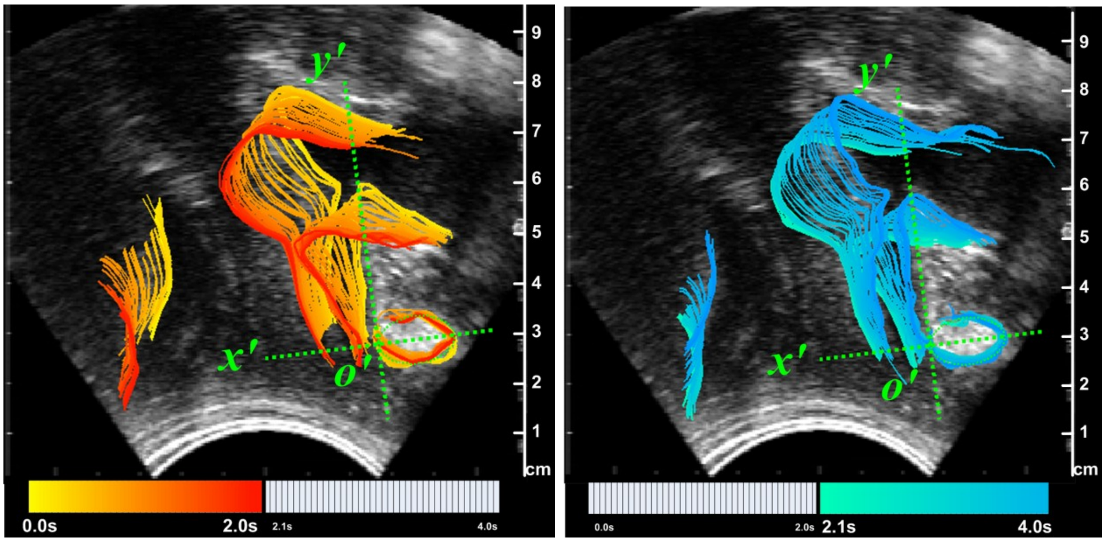


Figure 4.10: Effect of Valsalva showing the movement of the anterior and posterior edges of the UVJ and the ARA during (a) Valsalva and (b) release.

Displacement, velocity and acceleration:

During all manoeuvres, it was possible to measure: the magnitude, degree and direction of displacement of the urogenital structures; whether the speed of voluntary contraction affects these parameters; and whether or not the volunteer's structures return to their starting, resting position after completing the contraction.

Cough: During the coughs, the displacement of the positions on the urethra and ARA are almost the same in the x' direction, although the velocity and acceleration of the position on the posterior edges of the UVJ is smaller (Figure 4.11). In the y' direction, there is a significant difference between both edges of the UVJ when compared to the position on the ARA.

Voluntary PFM: During the contractions, the position on the ARA had the biggest displacement, the highest velocity and the highest acceleration in x' direction (Figure 4.12). The position on the posterior edges of the UVJ had the smallest displacement, the lowest velocity and the lowest acceleration in x' direction. In y' direction, the position on the ARA has more displacement than the positions on the anterior and posterior edges of the UVJ.

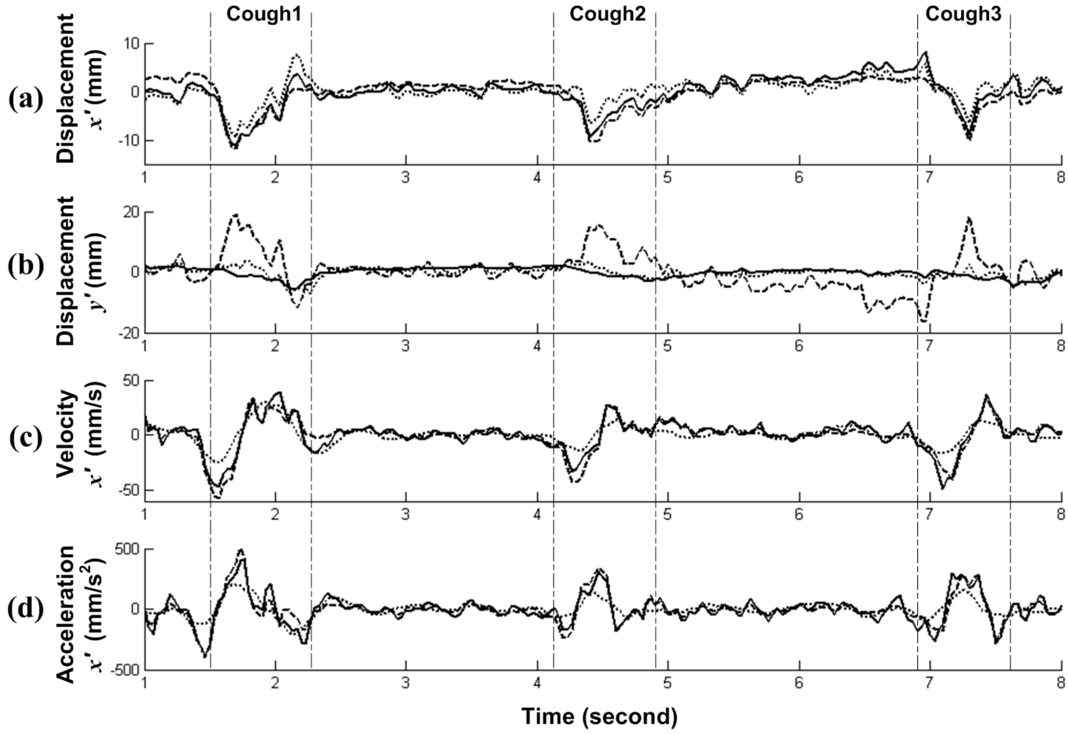


Figure 4.11: Cough: The displacement in x' direction (a), the movement in y' direction (b), the velocity in x' direction (c) and the acceleration in x' direction (d) of the position on the anterior edges of the UVJ (solid line), the posterior edges of the UVJ (dotted line) and the ARA (dash line). Three coughs are marked by cough1, cough2 and cough3 respectively.

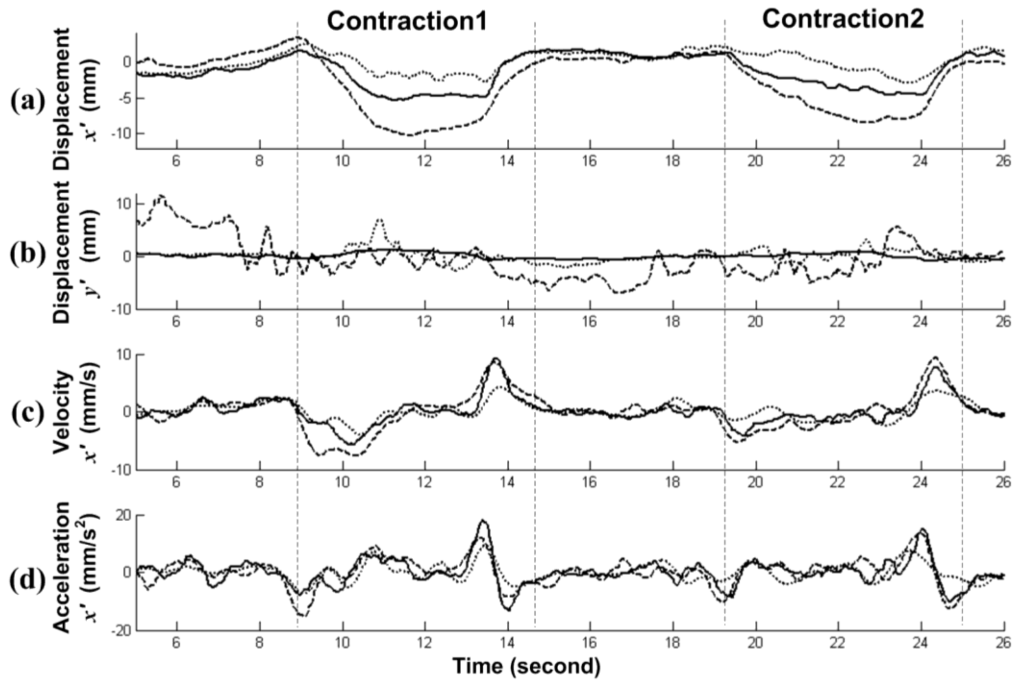


Figure 4.12: Voluntary PFM: The displacement in x' direction (a), the displacement in y' direction (b), the velocity in x' direction (c) and the acceleration in x' direction (d) of the position on the anterior edges of the UVJ (solid line), the posterior edges of the UVJ (dotted line) and the ARA (dash line). Two contractions are marked by contraction1 and contraction2 respectively.

Valsalva: During the Valsalva, the displacement of the three positions are similar in x' direction (Figure 4.13). The velocity and acceleration of the three positions are noisy but similar to each other. In y' direction, the position on the ARA has slightly more displacement than the positions on the anterior and posterior edges of the UVJ.

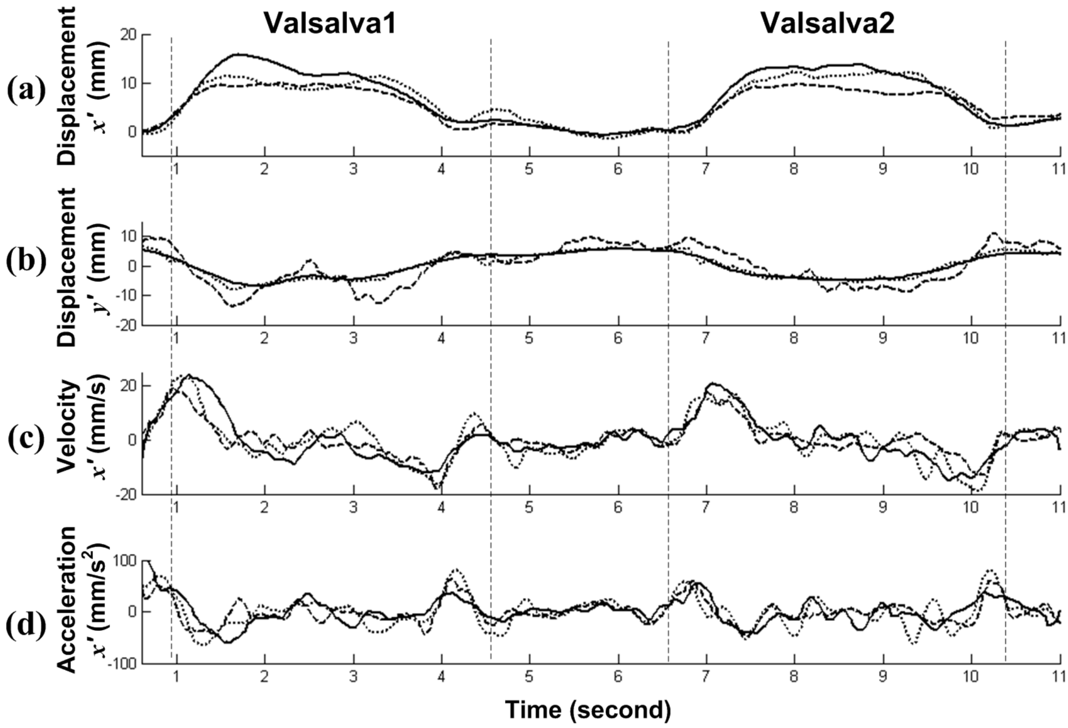
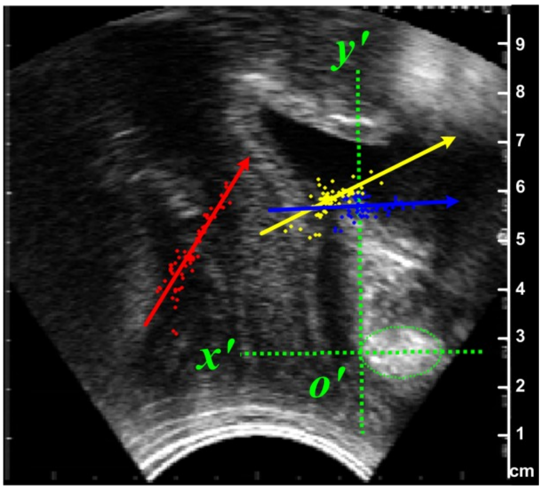


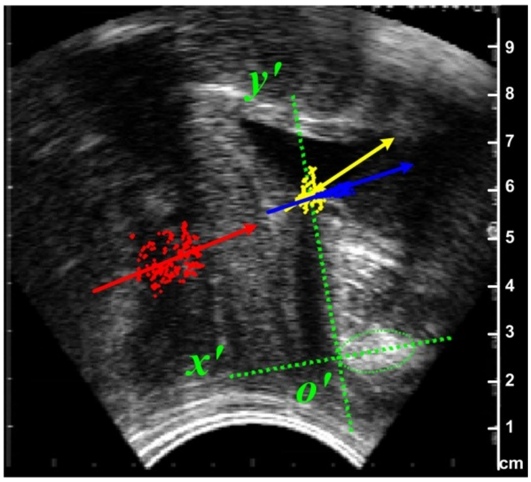
Figure 4.13: Valsalva: The displacement in x' direction (a), the displacement in y' direction (b), the velocity in x' direction (c) and the acceleration in x' direction (d) of the position on the anterior edges of the UVJ (solid line), the position on the posterior edges of the UVJ (dotted line) and the position on the ARA(dash line). Two Valsalvas are marked by Valsalva1 and Valsalva2 respectively.

The trajectories of the three positions during cough, contraction and Valsalva were then described qualitatively by linear regression. In the initial 0.3 seconds of the cough and in a voluntary PFM contraction, the directions of the movements of the positions on the anterior and posterior edges of the UVJ are similar (Figure 4.14, 4.15). However there is a difference between the direction and magnitude of displacement of the ARA during cough and PFM contraction, suggesting different mechanisms during reflex mediated contraction and voluntary PFM contraction. In Valsalva, all three edges move in the opposite directions as compared with the first 0.3 seconds of cough and voluntary PFM contraction.

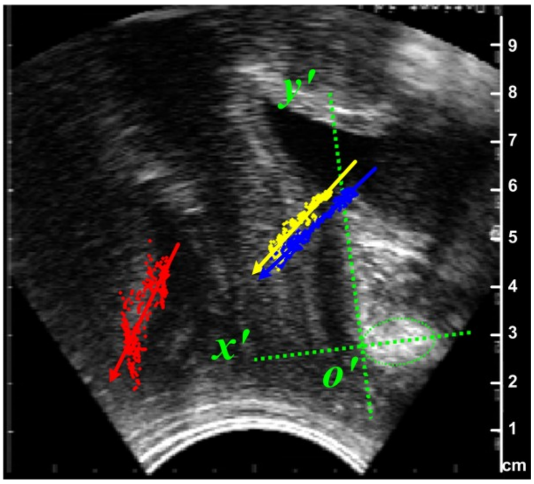
The displacements of 8 evenly-spaced positions (Figure 4.14d) on the anterior and posterior edges of the urethra during coughs, contractions and Valsalvas are shown graphically in Figure 4.16. The greatest X displacement occurs at the more proximal end of the urethra at the UVJ (position 8).



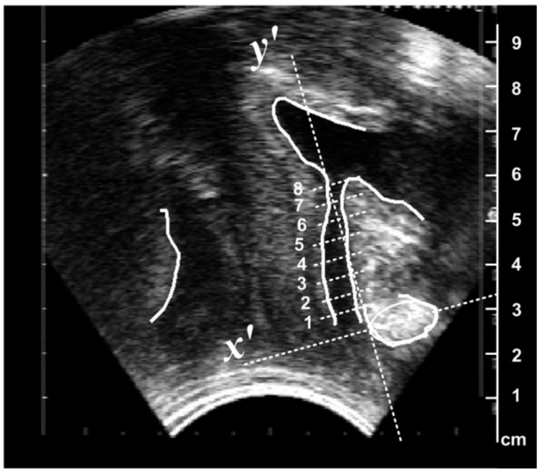
(a) Cough



(b) Contraction



(c) Valsalva



(d)

Figure 4.14: The directions of the movement of the three positions on the ultrasound images. The coordinate system fixed on the posterior inferior margin of the symphysis pubis is shown by the green dotted lines. The trajectories of the positions on the anterior and posterior edges of the UVJ and the position on the ARA are shown in blue dots, yellow dots and red dots respectively. The directions of their movement derived by linear regression are shown by blue arrows, yellow arrows and red arrows respectively. The arrows point to the direction of the movements where the corresponding manoeuvres start. (a) The movement during the first 0.3 seconds of cough; (b) The movement during contraction; (c) The movement during Valsalva; (d) 8 evenly-spaced positions on the anterior and posterior edge of the urethra.

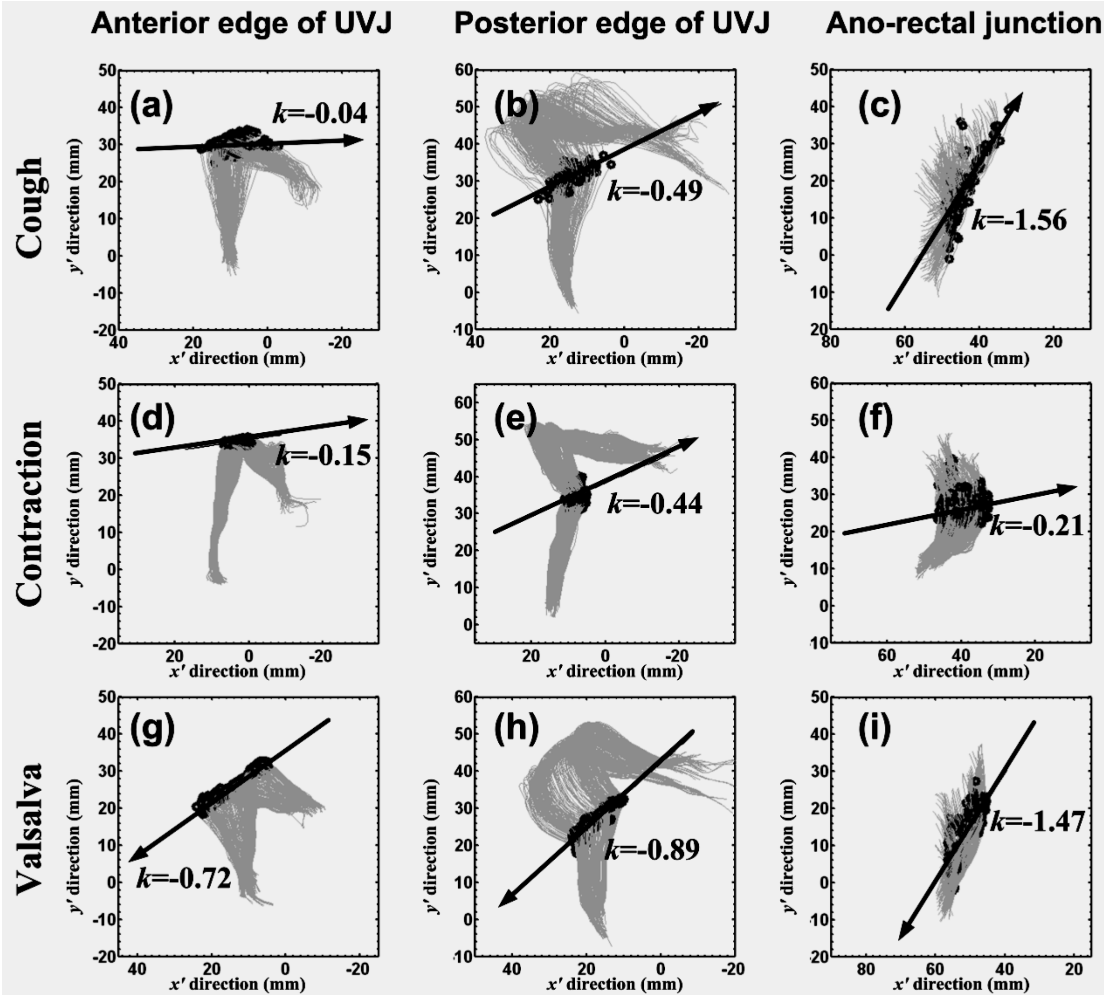


Figure 4.15: The direction of the movement of the positions on the anterior and posterior edges of the UVJ and the position on the ARA during cough, contraction and Valsalva. The boundaries of anterior and posterior edges of urethra and the ARA during the movement are shown by the dark curves. The trajectories of the positions chosen to describe the movement of the edges are shown by the black dots. The directions of the movement derived by linear regression are shown by the arrows. The arrows point to the direction of the movements where the corresponding manoeuvres start. k is the slope of the linear regression of the direction of the movements. (a) the movement of the anterior edges of the UVJ in cough; (b) the movement of the posterior edges of the UVJ in cough; (c) the movement of ARA in cough; (d) the movement of the anterior edges of the UVJ in contraction; (e) the movement of the posterior edges of the UVJ in contraction; (f) the movement of ARA in contraction; (g) the movement of the anterior edges of the UVJ in Valsalva; (h) the movement of the posterior edges of the UVJ in Valsalva; (i) the movement of ARA in Valsalva.

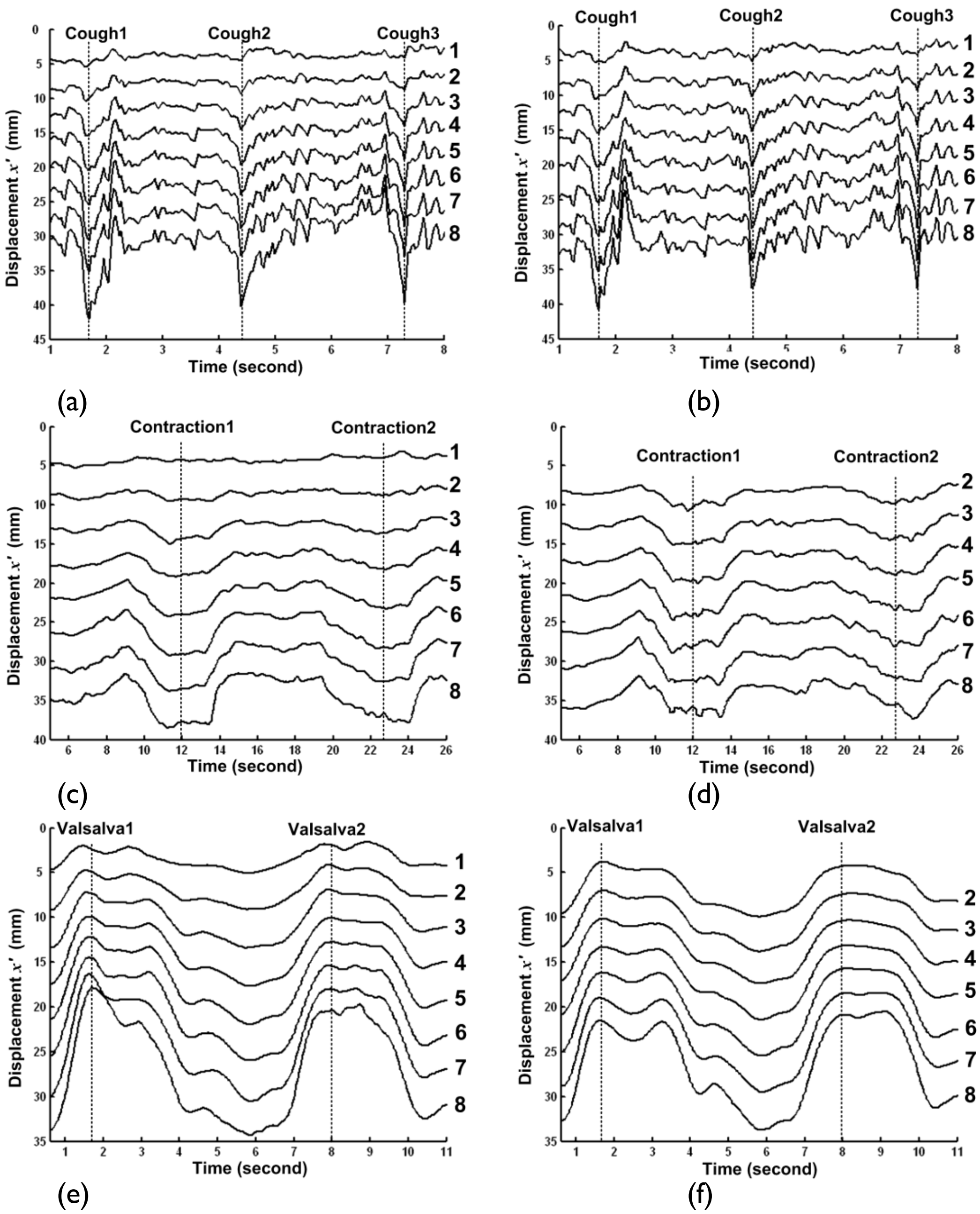


Figure 4.16: The displacement of 8 evenly-spaced positions on the anterior and posterior edges of the urethra during coughs (a, b), contractions (c, d) and Valsalvas (e, f). Y axis represents the displacement in x' direction. To avoid the overlap of the curves of the 8 selected positions, the displacement of each position is shifted a distance equals to its coordinate in y' direction. Position 1 on the posterior edges of the urethra during contractions (d) and Valsalvas (e) are not available because they are not clear in the ultrasound movies.

4.5 Discussion

Both methodologies were able to quantify novel dynamic parameters of PFM function such as displacement throughout the whole manoeuvre, velocity and acceleration and neither method relied upon the operator to capture the precise moment at the end of the manoeuvre. Speckle tracking was able to quantify displacement, velocity and acceleration of the ARA, but not the urethra. The segmentation methodology could quantitatively measure the urethra, bladder and rectal interfaces during manoeuvres and provided greater detail; however was very time intensive, particularly determining the apparent displacement of the SP and coordinate system.

The designation of the pubic bone central axis has been shown to be a considerable source of variance between investigators (Armstrong *et al.*, 2006) as it depends on the clarity of the ultrasound images and the researcher's experience to find a position on the SP to fix the origin point and to determine the orientation of the x and y axes. Both methodologies semi- automatically track the apparent motion of the SP, however, in the segmentation methodology, an ellipse-shape assumption of the SP was used to determine the origin point and the orientation of the x and y axis. The deviation of the pubis from the ellipse-shape assumption affects the position of the origin point and the orientation of the x and y axis. If the out-of-plane transducer rotation is negligible, the shape of the SP remains the same in different frames, but in less clear ultrasound images, the exact shape and registration of the SP is difficult to establish.

4.6 Summary

The feasibility of two image processing methods used to track PF structures during dynamic events has been shown. Segmentation provides the opportunity to quantify greater detail but is very labour intensive and relies upon a clear elliptical shape of the SP in each ultrasound frame to determine a fixed reference point. Speckle tracking is an easier, less time intensive methodology and does not rely upon a specific shape of the SP to determine a reference point. Unfortunately, speckle tracking is unable to track the urethra during fast events. Therefore for the experimental studies:

1. the coordinate system and tracking of the apparent motion of the SP described in the speckle tracking methodology is used as the reference point;
2. speckle tracking is used to measure the displacement of the ARA;
3. segmentation is used to measure the displacement of the urethra.

In the next chapter, the intra and inter-observer reliability of these image processing methodologies will be established.

5 Intra and Inter-observer Reliability of the Image Processing Methods

5.1 Introduction

In Chapter 4, we ascertained that the image processing techniques were feasible, yet for a measure to be useful it must provide accurate and meaningful results to clinicians and researchers; to be described as reliable, it also needs to be consistent. In order to strengthen the generalisability of the results of the image processing methodology in the future experimental chapters, and allow greater confidence in interpretation of the outcome, both intra and inter- observer reliability need to be established.

To date, no study has evaluated the displacement of the ano-rectal angle (ARA) during a cough, therefore no reliability studies exist. No study has evaluated the inter-observer reliability of urethral displacement during a cough in women with stress urinary incontinence (SUI), however two studies have evaluated the intra-observer reliability in asymptomatic volunteers; intraclass correlation coefficient (ICC) between 0.51 and 0.96 (Peschers *et al.*, 2001c;Braekken *et al.*, 2008). In the earlier study by Peschers et al, confidence intervals (CI) of 0.896 to 0.984 were also reported, and mean differences calculated using methods recommended by Bland and Altman (Bland & Altman, 1986). Differences did not exceed more than 4mm of displacement, less than 2 Standard Deviation (SD) from the mean. One other study group reported has satisfactory intra and inter-observer reliability in asymptomatic women for the change in urethrovesical junction (UVJ) angle during a cough, however, reliability was expressed as a SD in percentage of the estimate (Costantini *et al.*, 2005).

The reliability of ultrasound imaging has been investigated using a variety of statistical tests, most recently using a combination of intraclass correlation coefficients (ICC), with 95% Confidence Intervals (CI), standard error of measurement (SEM) and minimal detectable change (MDC) (Stokes *et al.*, 2005;Teyhen, 2006;Teyhen *et al.*, 2007;Whittaker *et al.*, 2007a;Koppenhaver *et al.*, 2009). Bland and Altman techniques are independent of the true variability in the observations and compliment the ICC values (Bland & Altman, 1990;Rankin & Stokes, 1998). They provide a clinically meaningful measure of the magnitude of agreement (95% limits of agreement) and easily identify systematic bias, outliers and any relationship between the variance in measures with the size of the mean (Bland & Altman, 1990;Rankin & Stokes, 1998). No single test is sufficient to reflect reliability fully and it has been recommended that future studies use all of these methods of analysis to enable comparison between reliability studies (Stokes *et al.*, 2005;Teyhen, 2006;Teyhen *et al.*, 2007;Whittaker *et al.*, 2007a;Koppenhaver *et al.*, 2009).

This chapter evaluates the intra and inter-observer reliability of processing the same transperineal (TP) ultrasound audio-visual image (AVI) files of a cough in continent and stress urinary incontinent (SUI) women, using speckle tracking and segmentation as described in Chapter 4.

5.2 Aims:

5.2.1 To establish the intra and inter-observer reliability of speckle tracking to measure the displacement of the ano-rectal angle (ARA) as described in pilot study 1 (Section 4.3)

5.2.2 To establish the intra and inter-observer reliability of segmentation to measure the displacement of the urethra as described in pilot study 2 (Section 4.4).

5.2.3 To evaluate the effect of altering the synchronisation method on the wave form and displacement values of the urethra.

5.3 Methods:

On two occasions separated by more than a month, RLJ evaluated the same AVI ultrasound files during a cough of ten continent and nine SUI women. The same AVI files were also evaluated by a second independent observer (QP), and both were blinded to each other's results. The AVI file of each subject had 2 or 3 coughs, separated by a rest period.

1. Speckle tracking was used to measure the apparent motion of the SP and displacement of the ARA (Pilot study 1, section 4.3);
2. Segmentation was used to measure the displacement of the urethra (Pilot study 2, section 4.4).

Statistical analysis to compare the results were performed on all the cough images that both QP and RLJ were able to extract from the ultrasound data. For example, for subject A, QP may have concluded that cough 1, 2 and 3 were acceptable wave forms produced from his image processing methods, whereas RLJ may have determined that cough 1 and 3 were acceptable from her independent processing methods. This would then result in only 2 coughs (cough 1 and 3 from patient A) being available for statistical comparison.

The wave forms produced by each observer are presented individually and the Standard Error of Measurement (SEM) was calculated for the average of the displacement values at the synchronisation point, as well as methods recommended by Bland and Altman (Bland & Altman, 1986), and ICC with 95% CI. The same AVI files (targets) were rated by the same two judges, who were the only judges of interest, so a two way mixed effect ICC model (ICC 3,1) was used. Bland & Altman analysis was evaluated with GraphPad Prism 5 and ICC with SSPS 16.0 for Windows Graduate Pack.

The effect of varying the synchronisation point on the wave forms, displacement values and subsequent statistical analysis were also evaluated. In the first two studies the graphs are aligned at the maximum caudal Y displacement, in the third, they are aligned at the maximum dorsal X displacement.

5.4 Results:

5.4.1 Speckle Tracking: (Pilot Study 1 section 4.3)

Using speckle tracking of the ARA and SP, the wave forms created by each observer to trace the displacement of the ARA in the dorso-ventral (X); caudo-cranial(Y) directions; and the resulting trajectory (R) are compared. The intra and inter-observer reliability for the displacement at the synchronisation point in these three directions are presented. There were 19 coughs images from ten continent and 18 cough images from nine incontinent women available for analysis.

5.4.1.1 Inter- observer reliability: The wave forms produced by each observer of the dorso-ventral, caudo-cranial displacements and trajectory of the ARA during a cough were all very similar. Visually, in the continent group, the wave forms of the observers almost perfectly match in all directions (Figure 5.1). In the SUI group, although there is less exact overlap of the wave forms, the match seems very reasonable (Figure 5.2). Mean ± Standard deviation (SD) of the ARA displacements at the synchronisation point are given for each observer (Table 5.1)

Continent wave forms: Visually, the wave forms of the observers almost perfectly match in all directions although there is a slight drift at the end of wave form (green QP) in the dorso-ventral direction indicated by the arrow (Figure 5.1a). In the polar plot which describes the exact trajectory of the ARA during a cough (Figure 5.1b) the green wave form does not return to the starting position in the centre of the polar plot.

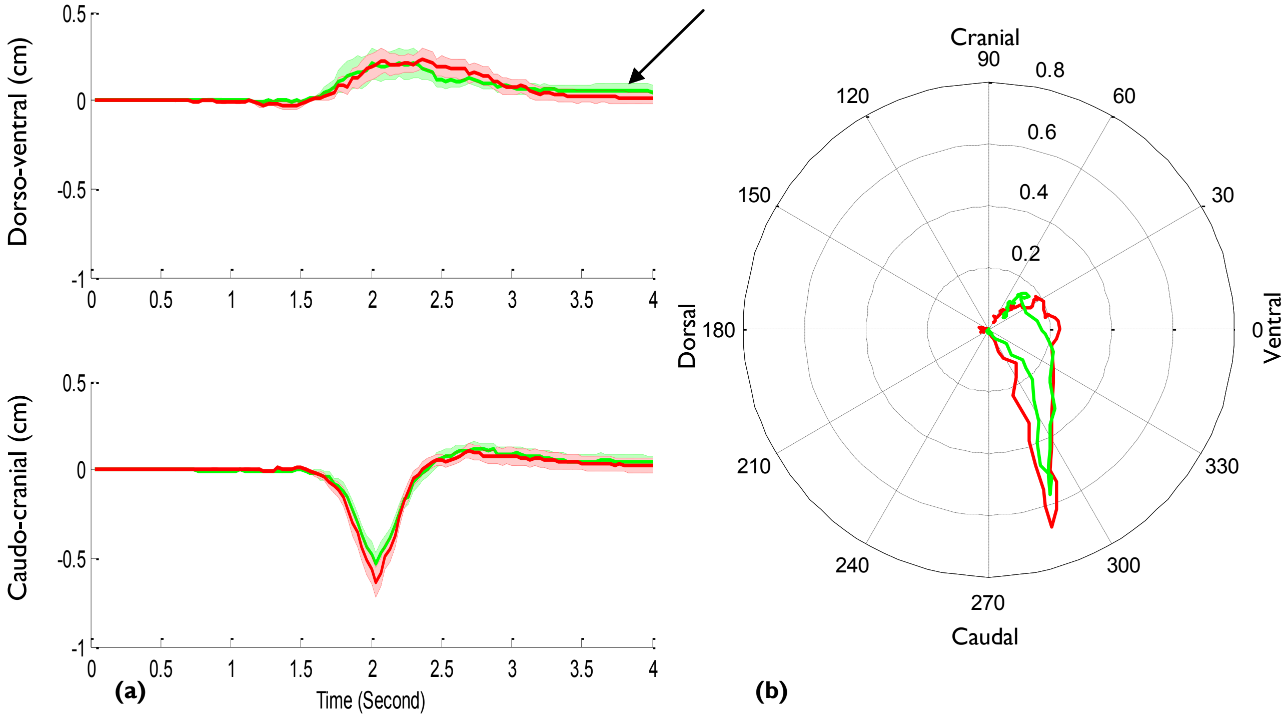


Figure 5.1: Comparison between two raters of the mean displacements and Standard Error (SE) in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the ARA measured by speckle tracking during a cough from 10 continent women in supine, synchronised by the time point of the maximum caudal displacement of Y. The observers QP and RLJ are shown in green and red respectively. Arrows indicate slight drift between observers at the end of the wave form.

Table 5.1: Mean and SD of the displacements of ARA at the synchronisation point during a cough (mean ± SD, Unit: cm) by two observers RLJ and QP, (Continent n=10: SUI n=9).

	Direction of ARA displacement	**Observer**	
		RLJ	QP
Continent	Dorso-ventral (X)	0.26 ± 0.36	0.28 ± 0.41
	Caudo-cranial(Y)	-0.55 ± 0.30	-0.41 ± 0.28
	Resultant (R)	0.66 ± 0.39	0.59 ± 0.37
SUI	Dorso-ventral (X)	-0.28 ± 0.30	-0.26 ± 0.25
	Caudo-cranial(Y)	-0.94 ± 0.52	1.18 ± 0.59
	Resultant (R)	1.01 ± 0.53	1.25 ± 0.55

SUI wave forms: Although there is less exact overlap of the wave forms compared to the continent group, the match is still very similar (Figure 5.2). In the caudo-cranial direction, the red wave form produced by RLJ appears a little higher throughout the manoeuvre, measuring slightly less displacement. Similarly in the red polar plot (Figure 5.2b) there is less overall displacement.

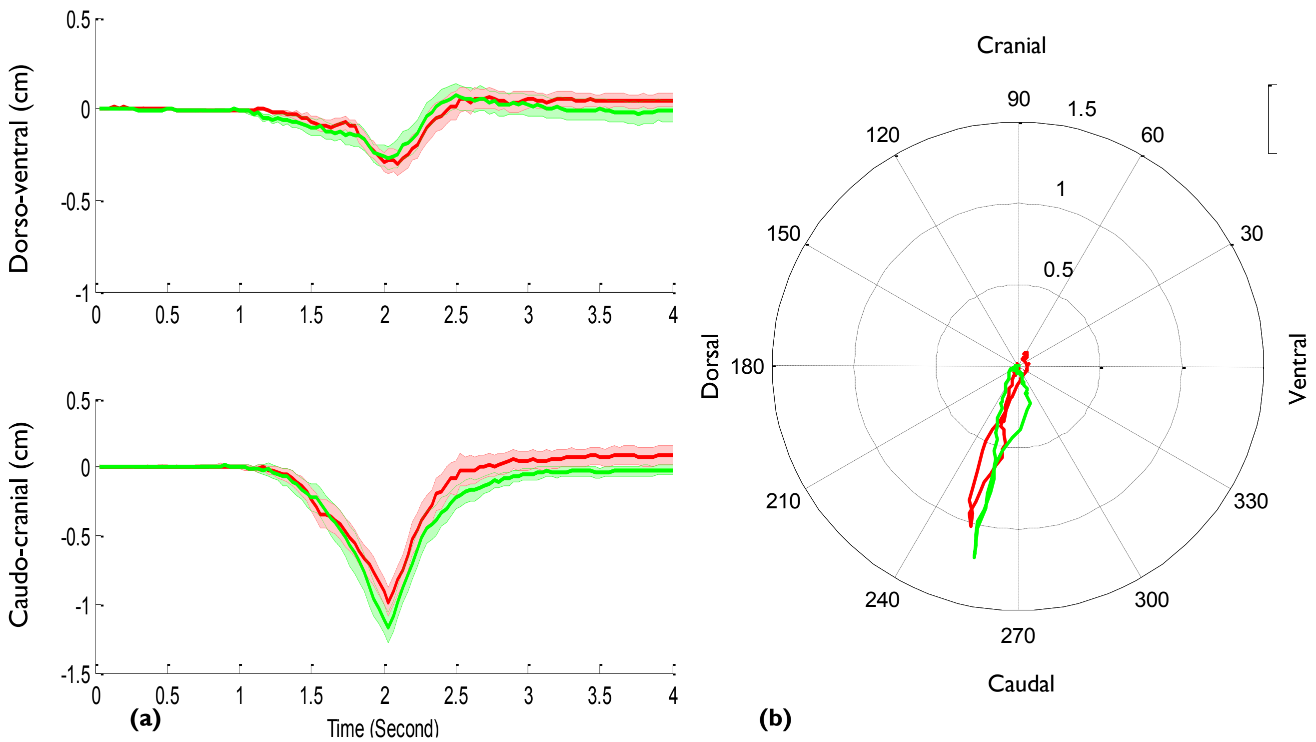


Figure 5.2: Comparison between two raters of the mean displacements and SE in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the ARA measured by speckle tracking during a cough from 9 SUI women in supine, synchronised by the time point of the maximum caudal displacement of Y. The observers QP and RLJ are shown in green and red respectively.

ICC statistical analysis (Table 5.2) indicates generally high agreement between observers for calculation of the displacement of the ARA at the synchronisation point at t = 2 seconds (range 0.58-0.96), with the exception of the dorsal-ventral (X) displacement of incontinent women, which was moderate (0.49-0.66), however as multiple assessments were used on a single subject, average measures (A) is the most appropriate ICC value to interpret (Streiner & Norman, 1995;Landis & Koch, 1977). Furthermore, even here, there was high agreement between measures on Bland & Altman (Bland, 1987).

Segmentation of the ARA shows greater inter-observer reliability in all directions for continent compared to SUI women.

Table 5.2: Inter-observer (RLJ) reliability analysis of ARA speckle tracking synchronised by maximum caudal displacement of Y. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, SE= Standard Error SD_{diff} = Standard Deviation of difference. SEM=standard error of measurement.

	ICC		**Bland Altman**				
Inter-observer reliability	ICC co	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Resultant (R) Continent **SEM=0.07**	0.80(S) 0.89(A)	0.38→0.95 0.55→0.97	0.03	0.07	-0.13→0.19	0.22	-0.49→0.20
Incontinent **SEM=0.21**	0.58(S) 0.73(A)	0.17→0.82 0.29→0.90	0.18	0.10	-0.03→0.38	0.42	-0.65→1.00
Dorsal-Ventral (X) Continent **SEM=0.03**	0.86(S) 0.93(A)	0.54→0.96 0.70→0.98	0.04	0.04	-0.06→0.13	0.13	-0.49→0.30
Incontinent **SEM=0.19**	0.49(S) 0.66(A)	-0.20→0.86 0.51→0.92	0.02	0.07	-0.14→0.18	0.32	-0.60→0.63
Caudo-cranial(Y) Continent **SEM=0.01**	0.92(S) 0.96(A)	0.72→0.98 0.84→0.98	-0.03	0.13	-0.12→0.06	0.04	-0.28→0.23
Incontinent **SEM=0.23**	0.57(S) 0.72(A)	0.15→0.81 0.26→0.90	-0.19	0.10	-0.40→0.02	0.43	-1.03→0.65

5.4.1.2 Intra-observer reliability (RLJ): Statistical analysis (Table 5.3) indicates good to excellent agreement in all directions (ICC = 0.67- 0.96) and is higher than the inter-observer reliability except for the resultant displacement (R) in the continent group, which was very similar.

Table 5.3: Intra-observer (RLJ) reliability analysis of ARA speckle tracking synchronised by maximum caudal displacement of Y. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. d = difference, SE= Standard Error SD_{diff} = Standard Deviation of difference. SEM=standard error of measurement

	ICC		Bland Altman				
Intra-observer reliability	ICC	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Resultant (R) Continent **SEM =0.07**	0.80(S) 0.89(A)	0.38→0.95 0.56→0.97	0.03	0.07	-0.13→0.19	0.22	-0.41→0.47
Incontinent **SEM =0.16**	0.67(S) 0.80(A)	0.06→0.91 0.11→0.96	0.35	0.12	-0.29→0.25	0.35	-0.71→0.68
Dorso-ventral (X) Continent **SEM =0.03**	0.93(S) 0.96(A)	0.74→0.98 0.85→0.99	0.04	0.04	-0.06→0.13	0.13	-0.22→0.29
Incontinent **SEM =0.07**	0.74(S) 0.85(A)	0.20→0.93 0.33→0.97	0.01	0.06	-0.14→0.15	0.19	-0.36→0.36
Caudo-cranial(Y) Continent **SEM =0.03**	0.92(S) 0.96(A)	0.72→0.98 0.84→0.99	-0.03	0.04	-0.12→0.06	0.13	-0.28→0.23
Incontinent **SEM =0.12**	0.73(S) 0.85(A)	0.19→0.93 0.32→0.97	-0.02	0.11	-0.27→0.22	0.32	-0.65→0.60

5.4.2 Urethral Segmentation: (Pilot Study 2 Section 4.4)

Using the segmentation methodology to trace the displacement of the urethra, the wave forms created by each observer in the dorso-ventral (X), caudo-cranial(Y) directions and the resulting trajectory (R) are compared. The intra and inter-observer reliability for the displacement at the synchronisation point at the maximum caudal displacement Y, in these three directions are presented. There were 23 coughs from 10 continent and 18 coughs from 9 incontinent women available for analysis.

5.4.2.1 Inter- observer reliability: The wave forms of the trajectory, dorso-ventral and caudo-cranial displacements of the urethra during a cough produced by each observer were all very similar (Figures 5.3 and 5.4).

Continent wave forms: In the continent group, visually the wave forms of the observers almost perfectly match in the caudo-cranial direction (Y), although there is a slight drift at the end of the green waveforms indicated by the arrows (Figure 5.3a). In the dorso-ventral direction (X), the overlap is not quite so exact, with the green wave form registering slightly greater displacement. The overall trajectory of the urethra displayed by the polar plot (Figure 5.3b) reflects the slightly bigger displacement of the green wave form.

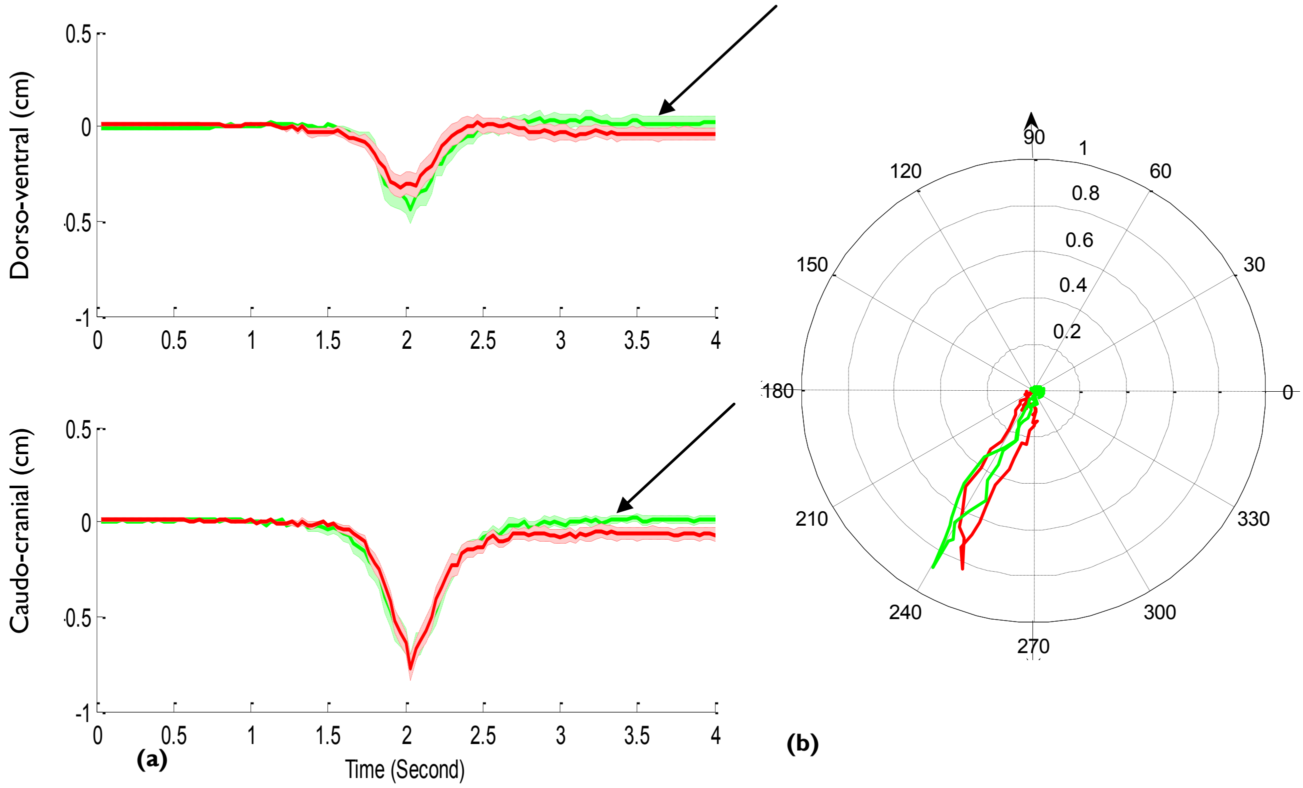


Figure 5.3: Comparison between two raters of the mean displacements and Standard Error (SE) in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the urethra measured by segmentation during a cough from 10 continent women in supine, synchronised by the time point of the maximum caudal displacement of Y. The observers QP and RLJ are shown in green and red respectively. Arrows indicate slight drift between observers at the end of the wave form.

Mean ± Standard deviation (SD) of the urethral displacements synchronised by the maximum caudal displacement of Y reflect that although there are slightly bigger maximum displacements recorded by QP, in the continent group they are less than 0.5mm and in the SUI group, less than 2mm (Table 5.4).

Table 5.4: Mean and SD of the displacements of the urethra at the synchronisation point (maximum caudal displacement of Y) during a cough (mean ± SD, Unit: cm) by two observers RLJ and QP, (Continent n=10: SUI n=9).

	Direction of urethral displacement	**Observer**	
		RLJ	QP
Continent	Dorso-ventral (X)	-0.32 ± 0.25	-0.34 ± 0.36
	Caudo-cranial(Y)	-0.67 ± 0.28	-0.63 ± 0.29
	Resultant (R)	0.77 ± 0.33	0.78 ± 0.34
SUI	Dorso-ventral (X)	-1.1 ± 0.44	-1.2 ± 0.55
	Caudo-cranial(Y)	-1.4 ± 0.59	-1.5 ± 0.55
	Resultant (R)	1.8 ± 0.65	2.0 ± 0.71

SUI wave forms: In the SUI group all wave forms match well (Figure 5.4). Once again, there is a slightly bigger displacement in the green wave form, although there is no drift at the end of the manoeuvre. In the polar plots, the overlap is extremely close until the maximum displacement, where the green wave form displays slightly greater displacement, whereas the red wave forms curves slightly more. Both wave forms finish at the starting point (Figure 5.4b).

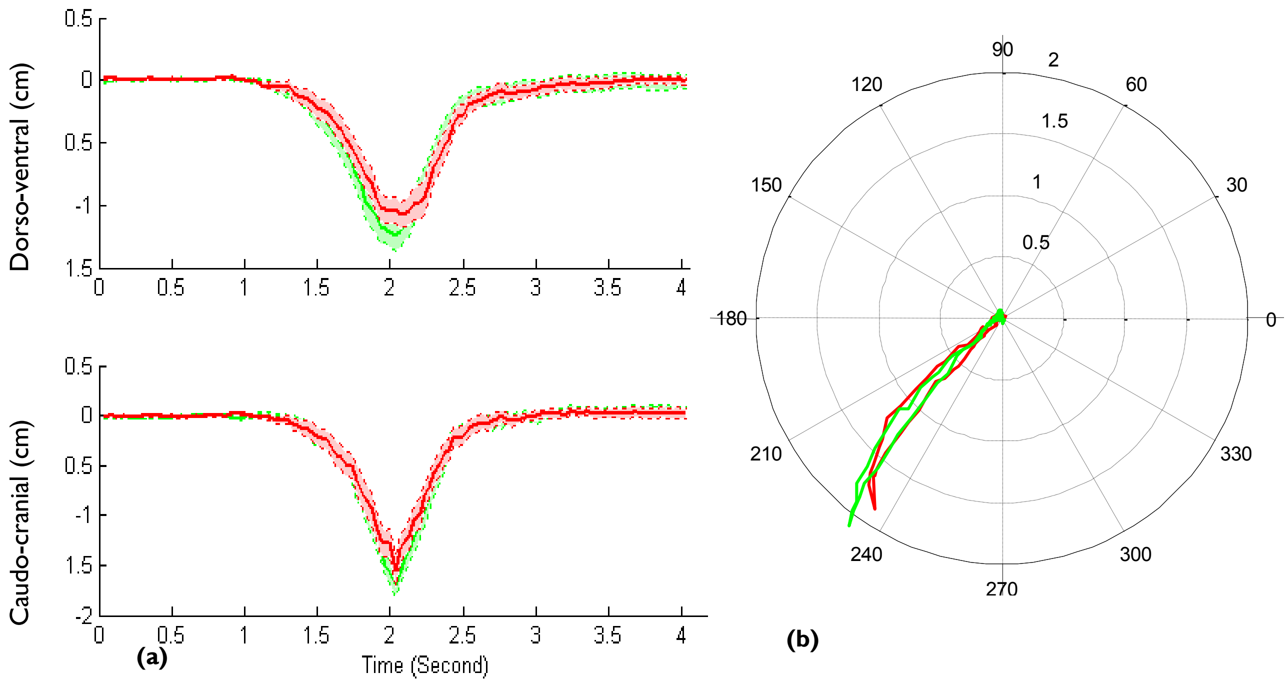


Figure 5.4: Comparison between two raters of the mean displacements and Standard Error (SE) in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the urethra measured by segmentation during a cough from 9 SUI women in supine, synchronised by the time point of the maximum caudal displacement of Y. The observers QP and RLJ are shown in green and red respectively.

Statistical analysis represents good to excellent agreement between observers (ICC = 0.61- 0.90) (SEM 0.04 cm to 0.21 cm) (Table 5.5). Segmentation of the urethra shows greater inter-observer reliability in the X direction for incontinent women compared to continent women, similar reliability between groups for the resultant, and better reliability in continent women compared to incontinent women in the Y direction.

Table 5.5: Inter-observer reliability analysis of urethral segmentation image processing methodology synchronised by maximum caudal displacement of Y. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, (SE)= Standard Error (SD_{diff})= Standard Deviation of difference. (SEM)= standard error of measurement

	ICC		**Bland Altman**				
Inter-observer reliability	ICC co	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Resultant (R)							
Continent **SEM=0.08**	0.79(S) 0.88(A)	0.56→0.90 0.72→0.95	0.03	0.05	-0.07→0.12	0.22	-0.42→0.47
Incontinent **SEM=0.16**	0.76(S) 0.86(A)	0.46→0.90 0.63→0.95	0.24	0.11	-0.01→0.47	0.47	-0.68→1.16
Dorso-ventral (X)							
Continent **SEM=0.18**	0.61(S) 0.76(A)	0.27→0.81 0.42→0.90	-0.03	0.08	-0.19→0.12	0.36	-0.74→0.68
Incontinent **SEM=0.10**	0.81(S) 0.89(A)	0.55→0.92 0.71→0.96	-0.13	0.07	-0.29→0.02	0.31	-0.75→0.48
Caudo-cranial(Y)							
Continent **SEM=0.04**	0.82(S) 0.90(A)	0.62→0.92 0.77→0.96	-0.04	0.14	-0.02→0.10	0.14	-0.24→0.31
Incontinent **SEM=0.21**	0.66(S) 0.80(A)	0.29→0.86 0.45→0.92	-0.21	0.11	-0.45→0.02	0.47	-1.13→0.71

5.4.2.2 Intra-observer Reliability (RLJ): There was excellent agreement in all directions in both groups (ICC = 0.93-0.99), (SEM 0.01 to 0.08cm) (Table 5.6).

Table 5.6: Intra-observer reliability analysis of urethral segmentation image processing methodology synchronised by maximum caudal displacement of Y. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, (SE)= Standard Error (SD_{diff})= Standard Deviation of difference. (SEM)= standard error of measurement

	ICC		Bland Altman				
Intra-observer reliability	ICC co	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Resultant (R)							
Continent	0.99(S)	0.94→0.99					
SEM=0.01	0.99(A)	0.97→0.99	-0.09	0.02	-0.14→0.05	0.07	-0.23→0.04
Incontinent	0.97(S)	0.87→0.99					
SEM=0.01	0.98(A)	0.93→0.99	0.17	0.04	0.07→0.26	0.13	-0.08→0.41
Dorso-ventral (X)							
Continent	0.94(S)	0.79→0.99					
SEM=0.02	0.97(A)	0.88→0.99	0.02	0.03	-0.04→0.08	0.09	-0.15→0.18
Incontinent	0.93(S)	0.74→0.99					
SEM=0.02	0.97(A)	0.85→0.99	0.03	0.04	-0.05→0.11	0.11	-0.18→0.24
Caudo-cranial(Y)							
Continent	0.97(S)	0.89→0.99					
SEM=0.01	0.99(A)	0.94→0.99	0.09	0.02	0.06→0.13	0.06	-0.01→0.20
Incontinent	0.97(S)	0.88→0.99					
SEM=0.08	0.99(A)	0.94→0.99	-0.19	0.05	-0.30→-0.09	0.47	-0.46→0.07

5.4.2.3 Urethral segmentation using alternative synchronisation point:

As the urethra in both continent and SUI groups were displaced in the same direction, there were two typical points in each wave forms that could be chosen as a synchronisation point; the maximum caudal or dorsal displacement. In the first urethral segmentation study above (Section 5.4.2), like the ARA analysis, the synchronisation point was defined as the maximum caudal displacement (Y). In this, the second urethral segmentation study, the synchronisation point was defined as the maximum dorsal displacement (X). In this way, the effect of altering the synchronisation point on the wave form and the subsequent statistical analysis was evaluated.

Segmentation of the urethra and synchronising with the maximum dorsal displacement X once again produced similar wave forms by each observer in both groups (Figure 5.5 and 5.6).

Continent wave form: In the continent group, in the dorso-ventral direction X, the red wave form starts to move dorsally slightly before the green wave form. (Figure 5.5a indicated by dotted arrow). There is also a drift at the end of the manoeuvre in both the dorso-ventral and caudo-cranial directions indicated by the solid arrows. The trajectory displayed in the polar plot (Figure 5.5b) emphasises the greater displacement of the green wave form.

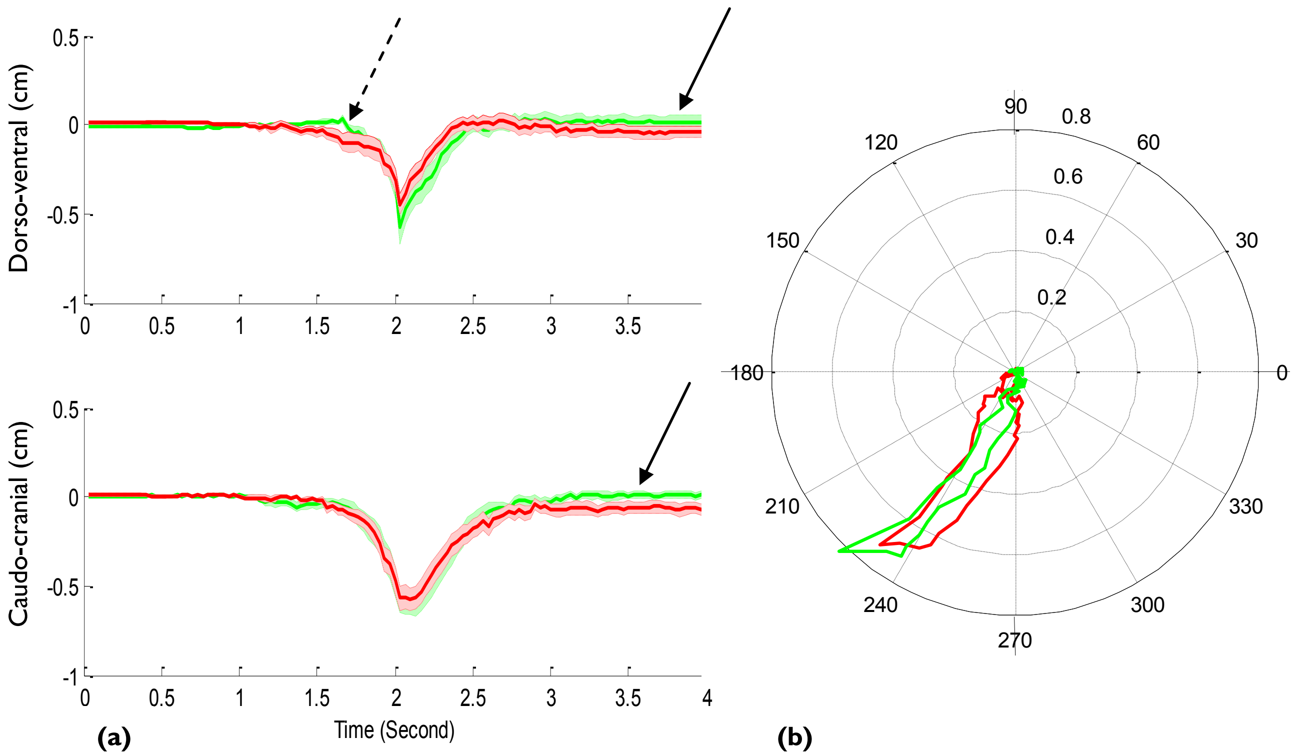


Figure 5.5: Comparison between two raters of the mean displacements and Standard Error (SE) in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the urethra measured by segmentation during a cough from 10 continent women in supine, synchronised by the time point of the maximum dorsal displacement of X. The observers QP and RLJ are shown in green and red respectively.

SUI wave form: Visually, the wave forms produced by each observer for the SUI group almost perfectly match in all directions, although in the green wave form (QP) there is very slightly more displacement, indicated particularly by the caudo-cranial displacement and polar plot (Figure 5.6). Unlike the continent group, there is no drift at the end of the manoeuvres.

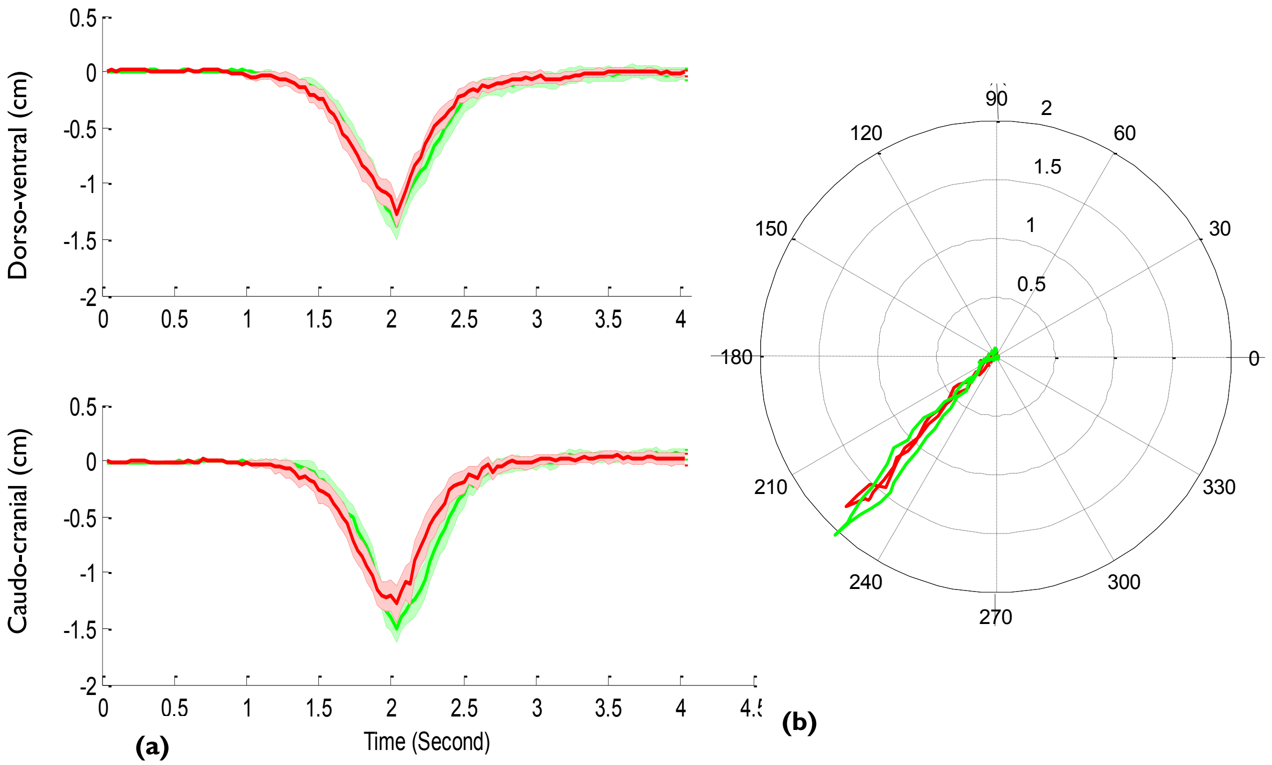


Figure 5.6: Comparison between two raters of the mean displacements and Standard Error (SE) in (a) Ventro-dorsal (X) and caudo-cranial(Y) directions and (b) trajectory (R) of the urethra measured by segmentation during a cough from 9 SUI women in supine, synchronised by the time point of the maximum dorsal displacement of X. The observers QP and RLJ are shown in green and red respectively. Arrows indicate slight drift in the wave form.

Mean ± Standard deviation (SD) of the urethral displacements synchronised by the maximum dorsal displacement of X are given for each observer and reflect that although there are slightly bigger maximum displacements recorded by QP, they do not exceed 0.1mm in the continent group or 0.2mm in the SUI group (Table 5.7).

Table 5.7: Mean and SD of the displacements of the urethra at the synchronisation point (maximum caudal displacement of X) during a cough (mean ± SD, Unit: cm) by two observers RLJ and QP, (Continent n=10: SUI n=9).

	Direction of urethral displacement	**Observer**	
		RLJ	QP
Continent	Dorso-ventral (X)	-0.38 ± 0.28	-0.47 ± 0.39
	Caudo-cranial(Y)	-0.56 ± 0.33	-0.59 ± 0.31
	Resultant (R)	0.71 ± 0.36	0.81 ± 0.39
SUI	Dorso-ventral (X)	-1.2 ± 0.49	-1.2 ± 0.51
	Caudo-cranial(Y)	-1.2 ± 0.60	-1.4 ± 0.49
	Resultant (R)	1.7 ± 0.64	1.9 ± 0.63

The statistical analysis reflects the close fit of the wave forms and indicates good to excellent agreement between observers in all directions (ICC 0.61-0.91) (SEM 0.06 to 0.25cm) (Table 5.8).

Table 5.8: Inter-observer reliability analysis of urethral segmentation image processing methodology synchronised by maximum caudal displacement of X. (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, (SE)= Standard Error (SD_{diff})= Standard Deviation of difference. (SEM)=standard error of measurement

	ICC		**Bland Altman**				
Inter-observer reliability	ICC	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% L.O.A (cm)
Resultant (R)							
Continent **SEM =0.12**	0.68(S) 0.81(A)	0.48→0.88 0.65→0.94	0.09	0.06	-0.02→0.21	0.27	-0.44→0.63
Incontinent **SEM =0.15**	0.78(S) 0.88(A)	0.51→0.91 0.68→0.96	0.18	0.10	-0.03→0.39	0.42	-0.64→1.00
Dorso-ventral (X)							
Continent **SEM =0.15**	0.61(S) 0.76(A)	0.27→0.81 0.42→0.90	-0.09	0.30	-0.22→0.04	0.30	-0.69→0.50
Incontinent **SEM =0.11**	0.79(S) 0.88(A)	0.52→0.92 0.69→0.96	-0.06	0.08	-0.22→0.10	0.33	-0.70→0.58
Caudo-cranial (Y)							
Continent **SEM =0.06**	0.83(S) 0.91(A)	0.65→0.93 0.79→0.97	-0.03	0.04	-0.11→0.05	0.19	-0.39→0.33
Incontinent **SEM =0.25**	0.60(S) 0.75(A)	0.20→0.83 0.33→0.91	-0.23	0.11	-0.47→0.02	0.50	-1.20→0.74

At the synchronisation point, segmentation of the urethra shows greater inter-observer reliability for the resultant R and dorso-ventral displacement X for SUI women, and better reliability in continent women in the Y direction.

The effect upon the wave form by altering the synchronisation point was to make the wave form more acute in which ever direction the displacements were synchronised. For example, if they were synchronised by the maximum dorsal displacement X, the graphs were more acute in the dorso-ventral direction (Figures 5.5a, 5.6a). When the maximum caudal displacement Y was used, the caudo-cranial wave form was more acute at the synchronisation point (Figure 5.3a, 5.4a). Statistically, there was little real change.

5.5 Discussion:

5.5.1 General Observations: This is the first study to describe the whole displacement of the ARA and urethra a cough, and the wave forms between observers are precise enough to be able to confidently describe the trajectory that the urogenital structures take. Intra-observer reliability was excellent for the segmentation methodology of the urethra, with ICC values between 0.94 and 0.99 and SEM from 0.01 to 0.08 cm. The ICC values are better than those more recently reported for displacement of the urethra during a cough in continent women (ICC 0.51)(Braekken *et al.*, 2008) , and very similar to an earlier study (ICC 0.96) (Peschers *et al.*, 2001c). This current study is the first to report inter-observer reliability for a cough, and the ICC and SEM were good to excellent, ICC between 0.61 and 0.90, SEM 0.04 and 0.25 cm.

Intra-observer reliability for speckle tracking of the ARA was also good to excellent, with ICC values between 0.67 and 0.96, SEM from 0.03 to 0.12 cm. Inter-observer reliability was also substantial (ICC 0.58 - 0.96, SEM from 0.03 to 0.23 cm) with the exception of speckle tracking of the ARA of SUI women in the dorso-ventral direction (ICC 0.49 single measure 0.66 average measures, SEM 0.19 cm). However, even here, if one considers the clinical relevance of the SEM of less than 0.2 cm and the SD of the difference of 0.32cm and compare this to the mean differences of displacement values between continent and incontinent women of 0.59cm it appears that the difference between observers is clinically as well as statistically insignificant.

There are a number of observations which may explain why the reliability for displacement values of speckle tracking of the ARA and segmentation of the urethra during a cough in continent women is better than that of the SUI women. During a cough of women with SUI, the PFM do not appear to contract, so there is little to limit the downward force and acceleration of the urogenital structures, hence the pressure produced during a cough will move the transducer. More movement of the transducer will mean more short term out-of-plane rotation; the 2D images will be less clear throughout the manoeuvre, so the tissues will be less easily tracked by the computer programme. The difference in reliability between groups is less noticeable in the segmentation methodology because if the wave form jumps significantly between one or two frames, the methodology allows the operator to take the average position between the frames, and almost eliminates the out of focus frames.

Indeed in some instances, such as the dorso-ventral displacement X, the reliability statistics of the urethral segmentation in the SUI group are actually better, or equal to the continent group (Table 5.3, 5.5).

5.5.2 Possible sources of differences between observers: The next section discusses the potential sources of differences between observers and provides recommendations for the rest of the current and any future studies.

5.5.2.1 Definition and tracking of the urogenital structures: The most critical aspect of the accuracy of the image processing methodology is most likely the definition of the boundary of the SP. This is the reference point from which the displacement of the ARA and urethra is measured, and therefore the displacement values of both these structures will be affected by it. The computer tracks the movement of the SP defined by the observer, and produces a new AVI movie which shows both the speckle tracking and the wave form it produces. The more consistently the bone stays within its defined kernel, the less noisy, or smoother the speckle tracking wave form is, and the more accurate the measurement. This new AVI movie is reviewed by the examiner, and if the wave form produced by tracking of the SP is jumpy or noisy, the whole procedure is repeated until the observer is satisfied. In some original AVI files captured from the volunteers, there were artefacts, such as those caused by the ultrasound gel and short-time out-of-plane rotation, which means that the SP was harder to automatically trace by the computer, resulting in a noisier wave form. Therefore, the definition of the boundary of the SP, the judgement of the reviewer and the clarity of the original AVI files will affect the results of the tracking of the SP and displacement results of the ARA and urethra.

In theory, the tracking of the ARA should be more reliable than that of the bone, as the algorithm tracks the ARA more than once, and the results are averaged. However, the boundary of the ARA is sometimes not as clear as the bone, and definition of the boundary will once again be according to experience and judgement of the operator. RLJ is more used to observing ultrasound images and it is possible that the reviewers may have chosen slightly different positions to track the ARA. Although clear criterion for defining the SP, ARA and urethra were agreed between examiners, it is possible that with further training, or using observers with similar experience of observing TP ultrasound scans, may have reduced the effect of operator variance when defining the structures.

In the rest of the studies, in “noisy” AVI files, the effects of any out of plane rotation and artefacts on the SP will be minimised by tracking the SP several times and averaging the results.

5.5.2.2 Definition of the starting point of a cough: The definition of the starting point of a cough may be a source of variance between observers, even when the starting points are averaged. In the data analysis, the starting point of each cough was defined as the zero point of the coughs. If one observer consistently picked a starting point just at the beginning of the rise of the wave form, it would affect both the maximum displacement, and the drift of the wave form, as the zero point would always be a little higher (for example the dorso-ventral displacement in Figure 5.2a and caudo-cranial displacement in Figure 5.4a). In the same way, if the end point was defined before the true end of a cough, the structure being tracked or segmented would not return to the starting point even if in reality it did (Polar plot Figure 5.1b)

In order to average and compare the coughs with different duration, the ARA movement before the starting point and after the end point are assumed to be the same as those on the starting point and end point respectively. If the rest time between coughs is insufficient, all the data before the starting point and after the end point will be inaccurate. In order to synchronise the cough, the base line of the start and finish times is elongated when there is insufficient rest time between coughs, however it may result in a drift in the wave form (for example Figure 5.5a) .

Although we are unable to change the methodology in this current study, in future studies, the issues associated with the start and end point of any manoeuvre could be eliminated completely by having one manoeuvre per AVI file, instead of attempting to split the file into sections. Additionally having an independent trigger or reference signal such as a defined change in intra-abdominal pressure (IAP) or Electromyography (EMG) could eliminate this potential source of variance. The use of simultaneous EMG recordings or IAP could have provided enhanced information, such as indicating force amplitude and timing of PFM contraction in relation to IAP and displacement of the urethra and ARA. However insertion of any device into the vagina would artificially distort the PF and affect the image processing.

5.5.2.3 Definition of the synchronisation point of the coughs: An independent trigger would also help to synchronise the coughs, and would possibly eliminate some further observer variability. When the wave forms produced by tracking of the SP and ARA were a little noisy, it occasionally caused several peak caudal displacements in the waveform, or a slight drift in the synchronisation point. If there were two peaks close together one observer may have chosen the first peak, the other may have chosen the second. One peak may be misleading because it may have been at the point the bony landmark jumped and the decision has to be finally based on the operator's judgement. The frequency of the noise is too close to that of the useful signals so we are unable to use a method to digitally filter this noise. Therefore, using the current methodology, the definition of the synchronisation point is also dependent on the observers' experience and judgement.

In the segmentation methodology of the urethra, the synchronisation points of the coughs were defined as either the point when the maximum caudal displacement Y or dorsal displacement X occurred. Altering the synchronisation point from maximum caudal displacement of Y to maximum dorsal displacement of X did not significantly change the ICC or SEM values of the displacement, although it slightly improved the SEM from 0.18cm to 0.15cm in the continent group in the dorso-ventral direction X, even though the wave form matched less well Figure 5.6). Clearly, altering the synchronisation point does change the wave forms and in some instances the wave forms seem much better matched, and in other instances they did not. For example, in the SUI group, comparing Figure 5.4 and 5.6, the wave forms all look better matched when synchronised by X (Figure 5.6). However in the continent group, comparing Figure 5.3 and 5.5, the wave form had greater overlap when synchronised by Y (Figure 5.3), particularly in the dorso-ventral direction.

5.6 Summary

This chapter has evaluated the intra and inter-observer reliability of novel image processing methods to evaluate TP ultrasound images. As discussed in Chapter 2 Section 2.11.2.3, an earlier study thoroughly explored the reliability of TP ultrasound measurement in continent women (Armstrong *et al.*, 2006) . They concluded that previous methodologies of ultrasound measurement have been inherently flawed due to: the variability inherent in pinpointing the SP, the reference point and axis with which to obtain a recording of distance; the difficulty with accurately locating the UVJ: and the variability of the quality of ultrasound images. Our methodology eliminates the requirement to manually determine the fixed reference point, and the software programs are robust enough to deal with poor image quality. Armstrong (Armstrong *et al.*, 2006) did not test the reliability of measurement during a cough; however their detailed observations support our rationale for tracking the SP digitally rather than allowing our measurements to be subject to the variance of repeatedly identifying the central axis of the SP. Furthermore digital segmentation, used in this current study to identify the path of the urethra during a cough, significantly overcomes some of the difficulty of identifying the urethra whenever it is distorted during manoeuvres.

5.7 Conclusions:

The main conclusions drawn from this current study are that:

1. 2D TP ultrasound imaging combined with image processing methods is a reliable method to describe and measure the function of the PFM in women.

2. The reliability for displacement values at the synchronisation points are good to excellent and this is how the differences between groups in the main study will be compared. The improvements mentioned are of particular importance if or when we are able to quantitatively compare or analyse the whole of the waveform.

3. The speckle tracking methodology has generally better statistical inter-observer reliability than the segmentation methodology; however, it is unable to track the urethra due to the degree of deformation that occurs to the urethra during a cough. The SP is not clear in each subject's film, so registration of the reference point from which the measurement is taken, using the segmentation methodology, is impossible with current technology.

4. The maximum negative displacement of the cranial caudal displacement (Y) will be used as the synchronisation point as the ARA in continent women does not have a typical caudal displacement, unlike the ARA of SUI women, or the urethra in both groups of women.

5. From a clinical perspective, the drift that happens at the end of a manoeuvre may contain important clinical information, as the method currently stands, it is

inappropriate to be too forceful in any conclusions drawn from the observation. Future studies should either allow greater time between manoeuvres, or only capture one manoeuvre per AVI file.

6. Having an independent trigger may eliminate some of the variance between operators, and although it is not possible to do so in the current study, it is suggested that future studies attempt to do so.

7. Although both studies allow measurement and comprehension of the mechanical properties of the PF in vivo, with non-invasive, repeatable ultrasound techniques, one further limitation is the time taken to process the data, particularly compared to static images. With the rapidly advancing field of image processing, particularly outside the medical field, one can imagine that advanced techniques that are less time consuming are not too far away.

The two image processing methodologies have been shown to be feasible and reliable. In order for the measure to be useful for clinicians and researchers, it needs to have meaning and be able to discriminate between groups. The next chapter presents the dynamic evaluation of the PF during a cough using 2D TP ultrasound imaging combined with image processing. It interprets these findings, providing novel evidence of PFM function and dysfunction in SUI and determines the sensitivity and specificity of TP ultrasound imaging combined with image processing methods to discriminate between continent and women with SUI.

6 Effect of a Cough on the Pelvic Floor; Evaluated by Real Time Ultrasound and Image Processing Methods.

6.1 Introduction

Current measurement tools have had difficulty identifying the automatic physiological processes maintaining continence and many questions still remain about (PFM) function during automatic events. The PFM are thought to perform multiple functions; yet if the PFM have to balance continence and pelvic organ support (DeLancey, 1994;Armstrong *et al.*, 2006), spinal stability (Pool-Goudzwaard *et al.*, 2004), respiration (Hodges *et al.*, 2007) and containment of intra-abdominal pressure (IAP) (Hemborg *et al.*, 1985), then given the multi-purpose role of these muscles, the motor control challenge would be immense. The efficiency of the PFM would not only rely upon the anatomical integrity of the pelvic floor (PF), but would depend on the central nervous system (CNS) response to satisfy hierarchical demands of function, generating a coordinated response so that the muscles' activity occurs at the right time, with the appropriate level of force.

It is suggested that the PFM contribute to urinary continence by providing external support to the urethra (Ashton-miller & Delancey, 2007;DeLancey *et al.*, 2008). PFM contraction increases with the intensity of a cough (Amarenco *et al.*, 2005) and IAP generated during stress (Shafik *et al.*, 2003). The failure of the PFM to resist increases in IAP may contribute to the patho-physiology of stress urinary incontinence (SUI) and pelvic organ prolapse (DeLancey, 1994;Constantinou & Govan, 1982). In addition to sphincteric incompetence, urethral hyper-mobility is thought to be one of the causes of female SUI, yet it is also evident in many continent women (Peschers *et al.*, 2001a;Reed *et al.*, 2004).

A number of electromyography (EMG) studies have indicated that there is altered PFM activation patterns in women with SUI compared to healthy volunteers, with delayed activation; shorter activation periods; lack of response or paradoxical inhibition (Smith *et al.*, 2007a;Barbic *et al.*, 2003;Deindl *et al.*, 1994;Deffieux *et al.*, 2007). Yet one study has indicated that women with incontinence had increased PFM EMG compared to continent women both prior to and during stress associated with unexpected loading (Smith *et al.*, 2007b) and another concludes that the pre-programmed PFM activity may not be important in the maintenance of continence(Verelst & Leivseth, 2004a) .

To date, imaging studies to date have identified the displacement of PF structures that occurs between the initial rest and end positions for a cough, Valsalva, or a voluntary PFM contraction (Literature review, Section 2.11.2). The reliable novel image processing methods (IPM) described in Chapter 4 and 5 allow the opportunity to visualise the whole sequence and automatic dynamic action of the PFM and urethra during the cough reflex and other manoeuvres. This next experimental chapter describes the mechanisms of PFM function during a cough in continent and SUI women and the effect on the urethra and determines the sensitivity and sensitivity of transperineal (TP) ultrasound combined with image processing methods (IPM) to correctly identify those women with SUI.

6.2 Aims

6.2.1 To determine the temporal distribution of the displacement, velocity and acceleration of the PFM and the effect upon the urethra during a cough.

6.2.2 To determine the sensitivity and specificity of TP ultrasound combined with IPM to correctly identify women with SUI.

6.3 Hypothesis

6.3.1 Under normal conditions, the cough reflex regulates the response of the PFM so that there is a limit to the magnitude of the displacement, velocity and acceleration of the PF and urethra when compared to women with SUI. Subsequently the urethra of SUI women moves further and faster in response to a cough compared to that of continent women.

6.4 Methods

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3.

A convenience sample of thirty three female volunteers was recruited as described in Section 3.3. They were asked to void 1 hour before testing, then drink 450 ml of water and to refrain from voiding until after the test sequences. The investigators were blinded to the continence status of the volunteers, who after evaluation, were divided on the basis of history and self reported symptoms to asymptomatic: no reported incontinence; and to those with SUI with their continence severity defined by a 12 point scale (Sandvik *et al.*, 2000). One volunteer was excluded due to symptoms of overactive bladder (OAB), and the general demographic of the groups has been given in Table 3.1 Section 3.3.

All volunteers were tested by one operator, in supine lying with their hips and knees bent and supported, with one pillow under their head and if time allowed in standing with feet hip width apart.

6.4.1 Transperineal (TP) Ultrasound: The ultrasound transducer was covered in gel, covered by an un-powdered glove followed by more ultrasound gel before being placed on the perineum in a mid sagittal direction, orientating the transducer so that the clearest images of the urogenital structures were viewed (Figure 2.12). The exact position of the transducer on the perineum was dependent on the ultrasound image observed and was applied with sufficient skin pressure to maintain the location and orientation without distortion of pelvic structures (Schaer *et al.*, 1996). The volunteers were asked to do a perceived maximum cough three times with a 5 second rest between each.

6.4.2 Image Processing Methods: The segmentation methodology for the urethra (Section 4.4), motion tracking algorithms for the symphysis pubis (SP) and Ano-rectal Angle (ARA) (Section 4.3) have already been described. In summary, motion of the ARA and SP were measured by speckle tracking (Peng *et al.*, 2007a) and the boundaries of the anterior and posterior edges of urethra, are segmented in the binary images using an automatic segmentation algorithm (Peng *et al.*, 2006). Displacements of the urethra and ARA are measured with respect to an orthogonal coordinate system fixed on the SP, parallel and vertical to the urethra at rest (Figure 6.1). When the tissues move, the coordinate system will maintain its original position and the subsequent trajectory of urogenital structures can be measured relative to this fixed axis. In order to accurately map the trajectory of the ARA and urethra, the apparent motion of the SP, created by movement of the transducer during the cough, is tracked and subtracted from the displacements of the ARA and urethra.

6.4.3 Statistical analysis: Mean and Standard Error (SE) of the displacement, velocity and acceleration were calculated and presented graphically. Statistical comparisons using one-tailed unpaired T-tests, were performed to evaluate the mean values (+2 SD) and level of significant differences of the displacement, velocity and acceleration components between the two groups. Where the variances were unequal, Welch's correction was applied, and a level of $P < 0.05$ was considered significant. The sensitivity and specificity of a cough measured by TP ultrasound and IPM methods were determined by calculating the area under a receiver operator curve (ROC) for displacement values of the two groups, with 95% confidence intervals (CI) and their P values. GraphPad Prism version 5.01 for Windows was used for statistical analysis.

6.4.4 Graph alignment:

Graphs are aligned so that the maximum caudal displacement occurs at time = 2 seconds. The data values in tables and statistical tests are calculated on the average of the maximum values from individual tests irrespective of time. In the first case we can see the maximum of the average, while in second case we calculate the average of the maxima, consequently the graphs do not correspond exactly with the tables. Angles are measured from the ventral axis so that the dorsal direction is 180° (-X), ventral is 0° (+X), cranial is 90° (-Y) and caudal 270° (+Y) (Figures 6.1, 6.2).

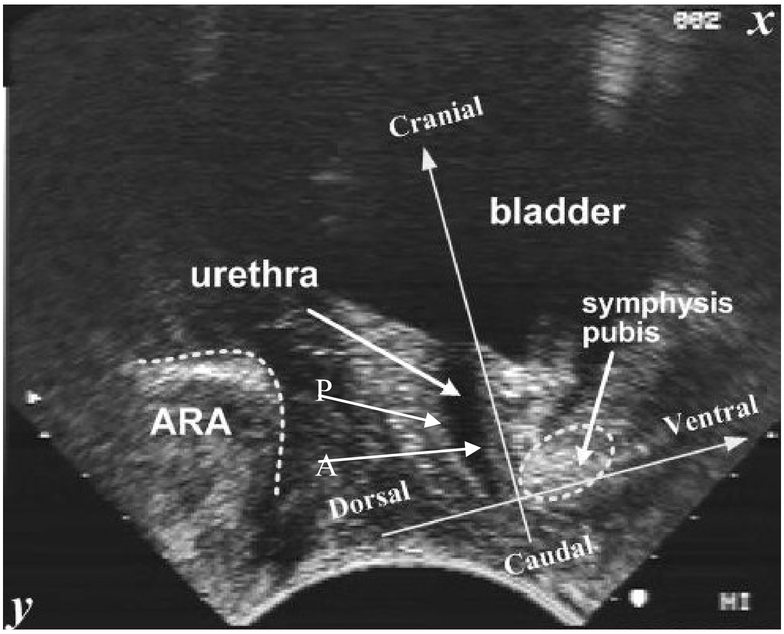


Figure 6.1: Typical transperineal view on an ultrasound scan with co-ordinate system placed on symphysis pubis, parallel and vertical to the urethra. P = posterior edge of the urethra; A= anterior edge of urethra.

6.5 Results:

The displacement of the urethra and ARA in twenty-three (23) continent women were analysed in supine, and sixteen (16) in standing. Nine (9) women with SUI were analysed in supine, five (5) in standing. ARA and urethral displacements were normally distributed in both the supine and standing positions.

6.5.1 Supine Displacement: When a continent women coughs in supine, the ARA moves in a ventro-caudal direction towards the SP, whereas the ARA and urethra of the SUI group moves in a dorso-caudal direction away from the SP (Figures 6.2, 6.3). The urethra in the continent group moves barely a third of the distance of the SUI group along a linear path and returns almost along the same path (Table 6.1, Figure 6.2). The urethra in the SUI group describes a more convoluted path, contrasting with the co-linear trajectory of the continent group.

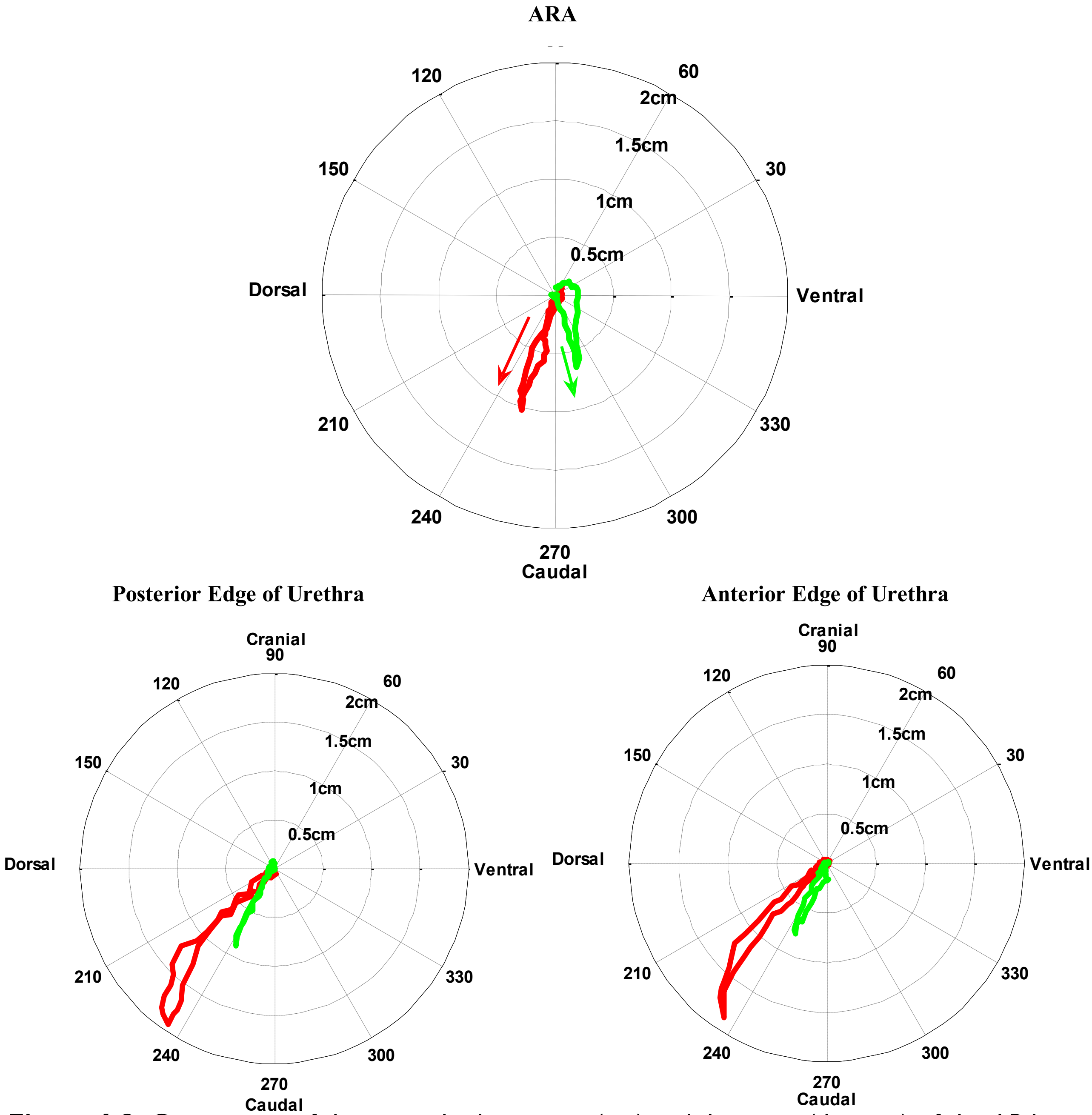


Figure 6.2: Comparison of the mean displacements (cm) and direction (degrees) of the ARA, and both edges of the urethra during a cough in supine continent (n = 23; green line) and SUI (n = 9; red line) women. The arrow in the ARA polar chart represents the initial direction of movement. Notice also the co-linear path of the urethra of continent women compared with the more convoluted trajectory of the urethra in the SUI group.

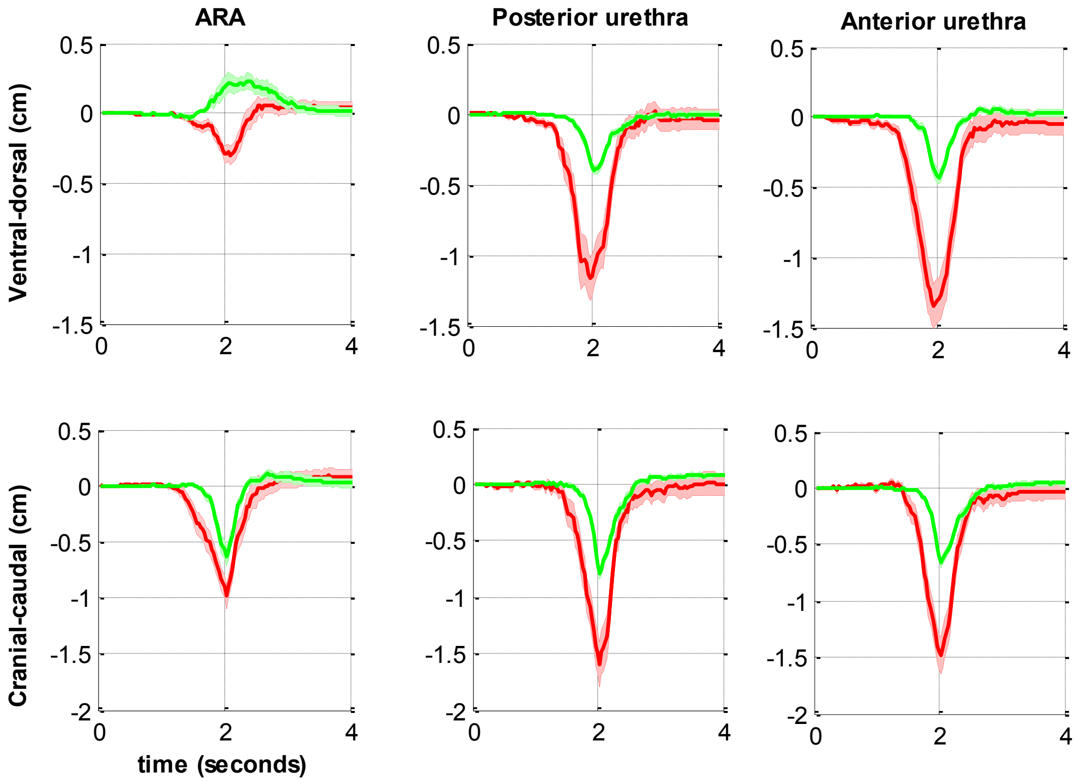


Figure 6.3: Comparison of the average displacements of the ARA, and both edges of the urethra during a cough in supine continent (n = 23; green line) and SUI (n = 9; red line) women. The shaded area represents the Standard Error (SE).

In the continent group, the anterior edge of the urethra moves significantly less than the posterior edge (P = 0.036) although there is no difference in the angle of displacement between edges (P = 0.51). In the SUI group, there is a significant difference of 10 degrees in displacement angle between the anterior and posterior edges of the urethra (P = 0.029) (Table 6.1).

Table 6.1: Mean and SD of the maximum displacements and angle of ARA and urethral displacement direction during a cough in supine (mean ± SD, Unit: cm; Angle: degrees).

	Dorsal -Ventral	Cranial-Caudal	Resultant	Angle (degrees)
ARA				
Continent	0.18 ± 0.36	-0.63 ± 0.37	0.77 ± 0.36	285 ± 40
SUI	-0.20 ± 0.26	-1.01 ± 0.42	1.1 ± 0.40	260 ± 20
P Value	**P = 0.0038**	**P = 0.0084**	**P = 0.022**	**P = 0.012**(UV)
Anterior				
Continent	-0.43 ± 0.28	-0.66 ± 0.25	0.84 ± 0.30	240 ± 15
SUI	-1.22 ± 0.48	-1.7 ± 0.51	2.1 ± 0.65	235 ± 10
P Value	**<0.0001**	**P = 0.0002** (UV)	**P = 0.0002** (UV)	**NS** P = 0.16(UV)
Posterior				
Continent	-0.41 ± 0.21	-0.80 ± 0.27	0.92 ± 0.28	240 ± 10
SUI	-1.1 ± 0.42	-1.7 ± 0.61	2.0 ±0.71	240 ± 5
P Value	**P = 0.0009** (UV)	**P = 0.0014** (UV)	**P = 0.0009** (UV)	**NS** P = 0.15

(Continent n = 23 and SUI n = 9). (UV = Welch's correction applied for unequal variances)

6.5.2 Sensitivity and Specificity: The displacement values of the urethra during a cough produced the highest overall ability of TP ultrasound imaging combined with IPM to discriminate between those individuals with SUI and those who were continent. Using the caudal displacement values of the anterior edge of the urethra produces an almost perfect test, with an area of 0.98 ± 0.02 under the ROC curve, (CI 0.94 to 1.00) P < 0.001. Caudal displacements of -1.1 cm produce 95% specificity (CI 0.77 to 0.99); 100% sensitivity (CI 0.66 to 1.00) and a likelihood ratio of 20.0, implying that someone with a positive test is twenty times more likely to have SUI than someone with a negative test.

The displacement values of the ARA measured with TP ultrasound imaging combined with IPM was less able than the displacement values of the urethra to discriminate between those individuals with SUI and those who were continent. However the dorso-ventral displacements produced the most useful test; resulting in an area of 0.81 ± 0.08 under the ROC curve, (CI 0.65 to 0.97) P = 0.007. Ventral displacements of 0.08 cm produced 89% specificity (CI 0.51 to 0.99); 61% sensitivity (CI 0.38 to 0.80) and a likelihood ratio of 2.3. Dorsal displacements of -0.18 cm produced 67% specificity (CI 0.29 to 0.92); 91% sensitivity (CI 0.71 to 0.99) and a likelihood ratio of 7.7.

6.5.3 Supine velocity: Before the synchronization point (time of maximum caudal (-Y) displacement at time = 2 seconds) the ARA in the continent group moves at its maximum ventral velocity towards the SP whereas the ARA in the SUI group moves dorsally away (Table 6.2, Figure 6.4).

Table 6.2: Mean and SD of the maximum velocity of the ARA and urethra in supine during a cough before and after the synchronisation point (Mean ± SD, Unit: cm s^{-1}).

	Dorsal-Ventral		Caudal-Cranial	
ARA	**Before**	**After**	**Before**	**After**
Continent	1.8 ± 0.95	-1.3 ± 0.75	-2.9 ± 1.5	3.3 ± 1.4
SUI	-1.5 ± 0.66	2.2 ± 0.98	-3.6 ± 1.0	4.1 ± 1.5
P Value	**<0.0001**	**<0.0001**	**NS** P = 0.10	**NS** P = 0.085
Anterior				
Continent	-2.8 ± 1.4	2.8 ± 1.3	-3.4 ± 1.3	3.1 ± 1.0
SUI	-4.2 ± 1.3	4.5 ± 2.3	-5.1 ± 1.3	6.3 ± 2.6
P Value	**P = 0.011**	**P = 0.0072**	**P = 0.0015**	**P = 0.0031**
Posterior				
Continent	-2.5 ± 1.4	2.5 ± 1.2	-3.7 ± 1.4	4.2 ± 1.7
SUI	-3.9 ± 1.1	4.0 ± 2.1	-5.4 ± 1.6	5.8 ± 2.4
P Value	**P = 0.0021**	**P = 0.034 (UV)**	**P = 0.0044**	**P = 0.0041**

(Continent n = 23 and SUI n = 9). (UV = Welch's correction applied for unequal variances)

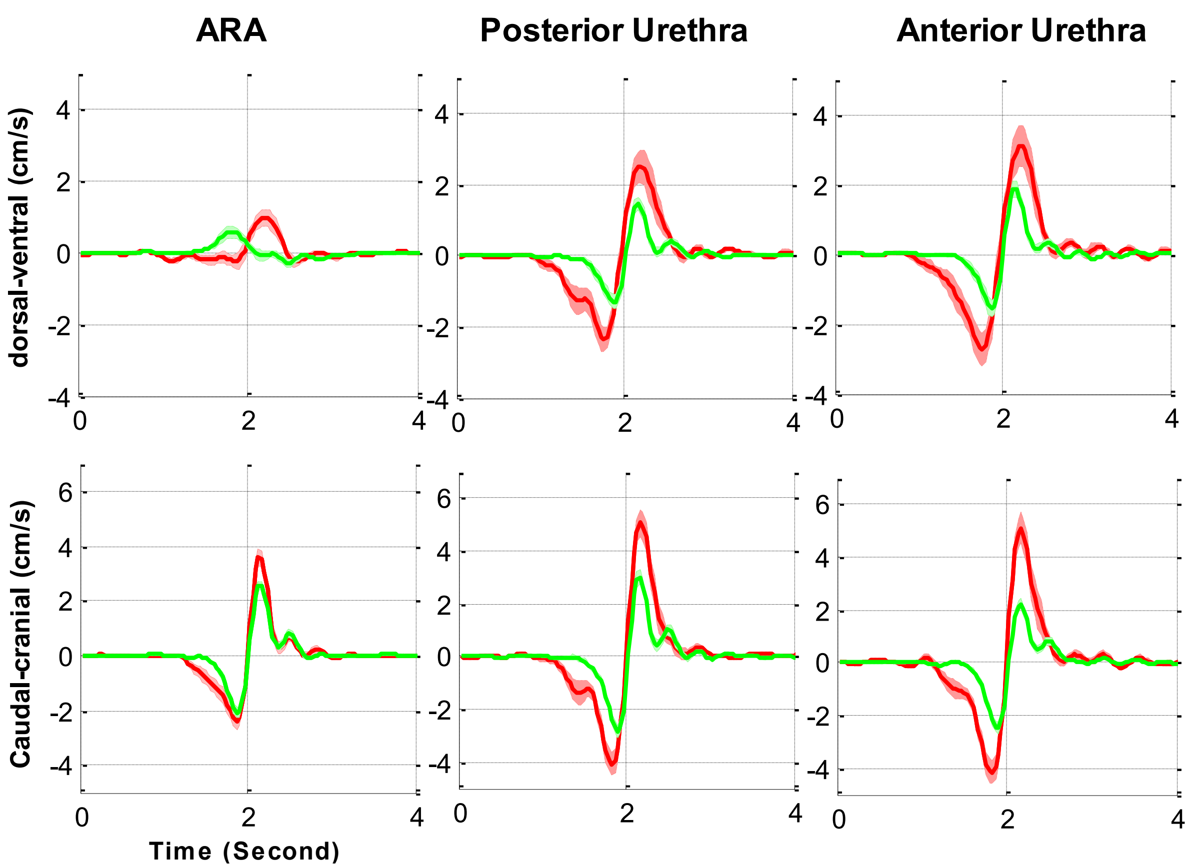
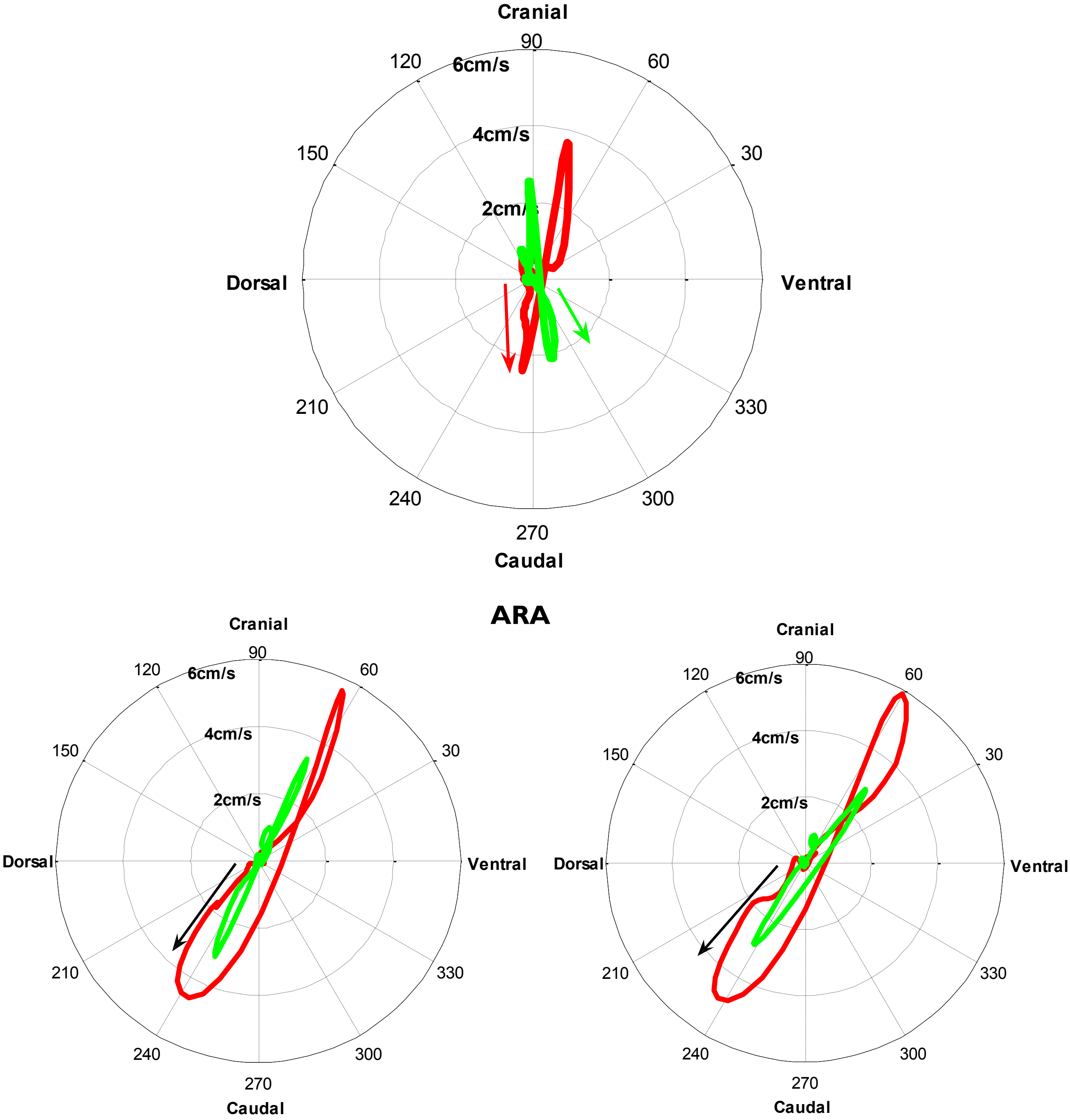


Figure 6.4: Comparison of the mean velocity (cms^{-1}) of the ARA, and both edges of the urethra during a cough in supine continent (n = 23; green line) and SUI (n = 9; red line) women. The shaded area represents the Standard Error (SE).

The ARA of the SUI group moves ventrally only after the maximum caudal displacement. The caudo-cranial velocity of the ARA in the incontinent group is higher, although not significantly different (Table 6.2). The urethra in both groups moves in a dorso-caudal direction, although the absolute angles and maximum velocity vary. Comparing the SUI to the asymptomatic group, in the dorsal-ventral direction the urethra moves with at least one and a half times the velocity and up to twice the caudo-cranial velocity (Table 6.2). The "rebound" occurs after the synchronisation point at t=2 seconds. In the continent group, the maximum velocities of the anterior urethra of continent women are the same or lower after the rebound, whereas they are larger after the rebound for the SUI cases. The duration of displacement of both the ARA and urethra is longer for the SUI group than the continent women (Figure 6.3, 6.4)

The disparity between groups can further be illustrated by plotting the amplitude and direction of the velocity of the ARA and urethra in polar plots (Figure 6.5). These graphs show the initial ventro-caudal velocity of the ARA in a continent women compared to the dorso-caudal movement of the ARA in women with SUI. Furthermore they highlight the additional transverse velocity of the urethra in the SUI group, absent in the co-linear path of the continent group.



Posterior Edge of Urethra **Anterior Edge of Urethra**

Figure 6.5: Comparison of the mean velocity (cms^{-1}) and direction (degrees) during a cough in supine of the (a) ARA and (b) both edges of the urethra: continent (n = 23; green line) and SUI (n = 9; red line) women. Arrows show initial general direction of velocities. In the SUI group, bigger transverse velocities exist indicated by the loops/kinks in the wave form.

6.5.4 Supine Acceleration: There is a tendency for the accelerations to be larger in the SUI group, although in general the magnitudes of the maximum accelerations between groups are more similar than the velocities and displacements (Table 6.3, Figure 6.6). The timing of the ARA acceleration is different between groups indicated by the initial small ventral acceleration of the ARA in the continent group compared to the negligible acceleration in the incontinent group (Figure 6.6). At the point when the caudal displacement is a maximum (t=2s), the ARA in both groups attain their maximum ventral-dorsal direction acceleration, but are accelerating in opposite directions.

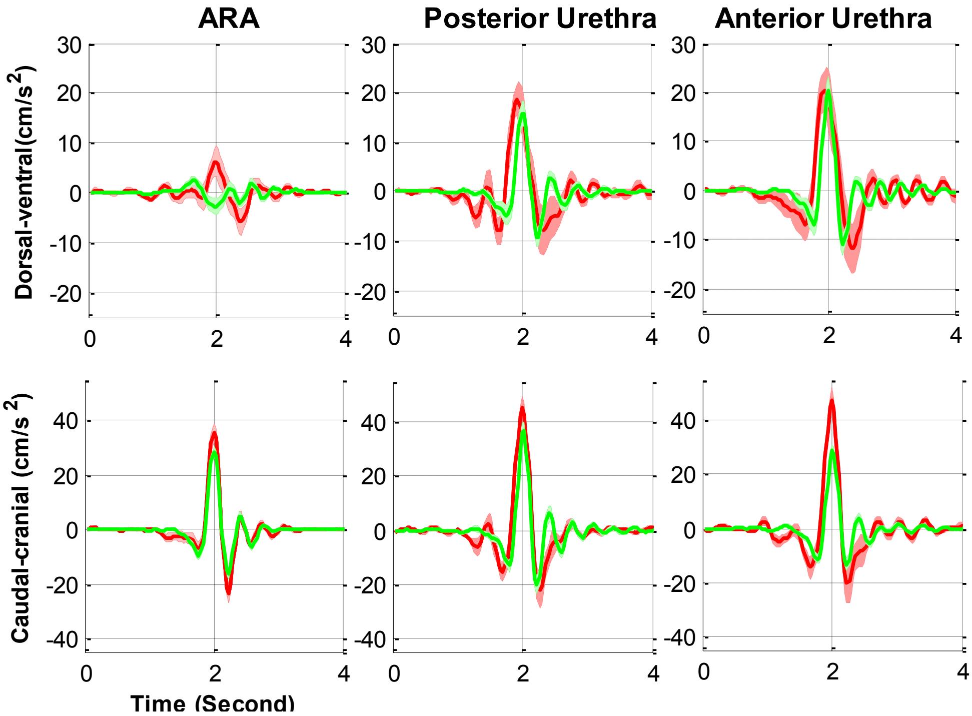


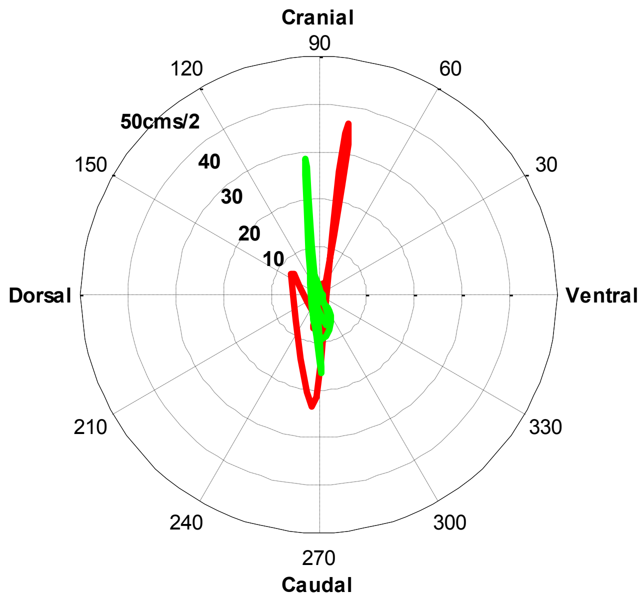
Figure 6.6: Comparison of the mean acceleration of the ARA, and both edges of the urethra during a cough in supine continent (n = 23; green line) and SUI (n = 9; red line) women. The shaded area represents the Standard Error (SE).

Table 6.3: Mean and SD of the maximum acceleration of the ARA and urethra in supine during a cough (Mean ± SD, Unit: cm s -2) (Continent n = 23 and SUI n = 9).

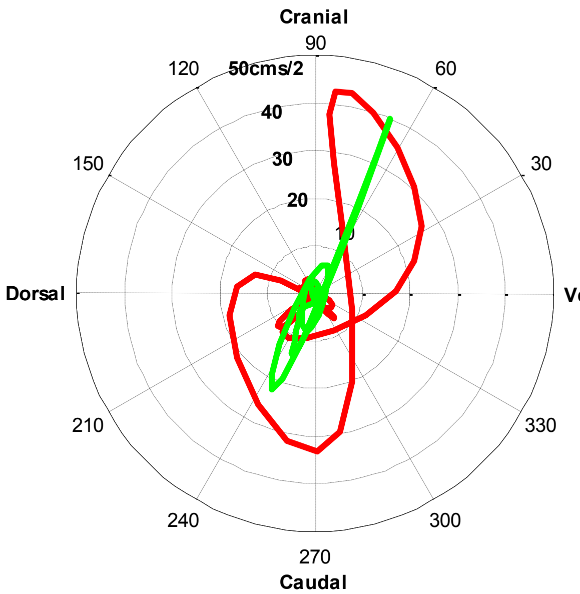
	Ventral	**Dorsal**	**Cranial**	**Caudal**
ARA				
Continent	15 ± 6.8	-18 ± 8.9	35 ± 18	-26 ± 12
SUI	24 ± 9.9	-21 ± 8.9	41 ± 13	-33 ± 8.6
P Value	**P = 0.015**	NS (P = 0.16)	NS (P = 0.20)	NS (P = 0.092)
Anterior Urethra				
Continent	35 ± 17	-25 ± 9.9	38 ± 13	-28 ± 9.4
SUI	39 ± 17	-34 ± 16	55 ± 19	-48 ± 21
P Value	NS (P = 0.27)	**P = 0.030**	**P = 0.0052**	**P = 0.012 (UV)**
Posterior Urethra				
Continent	31 ± 13	-24 ± 9.2	33 ± 24	-39 ± 16
SUI	37 ± 13	-34 ± 16	55 ± 16	-47 ± 16
P Value	NS (P = 0.11)	**P = 0.021**	**P = 0.0060**	**NS** P = 0.12

In a cranial-caudal direction there are no significant differences in the maximum accelerations. The maximum acceleration of the urethra in the continent group is less than the SUI group, particularly cranially and dorsally and although there is a significant difference in maximum acceleration of the anterior edge, caudally there is significant variance in the SUI group (Table 6.3).

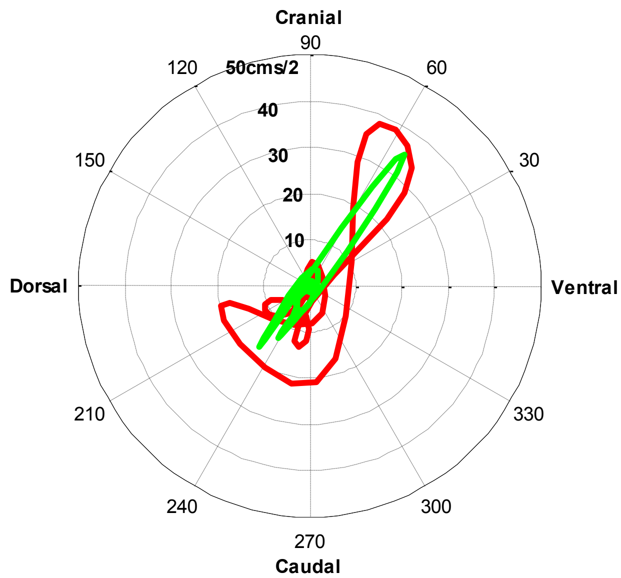
The uncontrolled transverse acceleration observed in the SUI group are particularly obvious in the ventral cranial direction, after the maximum cranial displacement (Figure 6.7) and contrast with the difference in co-linear acceleration of the ARA and edges of the urethra in the asymptomatic group.



ARA



Posterior Edge Urethra



Anterior Edge Urethra

Figure 6.7: Comparison of the mean acceleration (cms-2) and direction (degrees) of the ARA, and both edges of the urethra during a cough in supine continent (n = 23; green line) and SUI (n = 9; red line) women. In the SUI group, bigger transverse accelerations exist indicated by the loops/kinks in the wave form.

6.5.5 Standing Displacement: When the displacements of the PF structures between groups are compared directly (Figure 6.8, 6.9, Table 6.4) the differences between groups, in trajectory, magnitude and angle of displacement are apparent. When a continent women coughs, the ARA moves in a predominantly caudal direction after a slight ventral movement, whereas the ARA of the SUI group moves three times as far in dorso-cranial direction away from the symphysis pubis (SP).

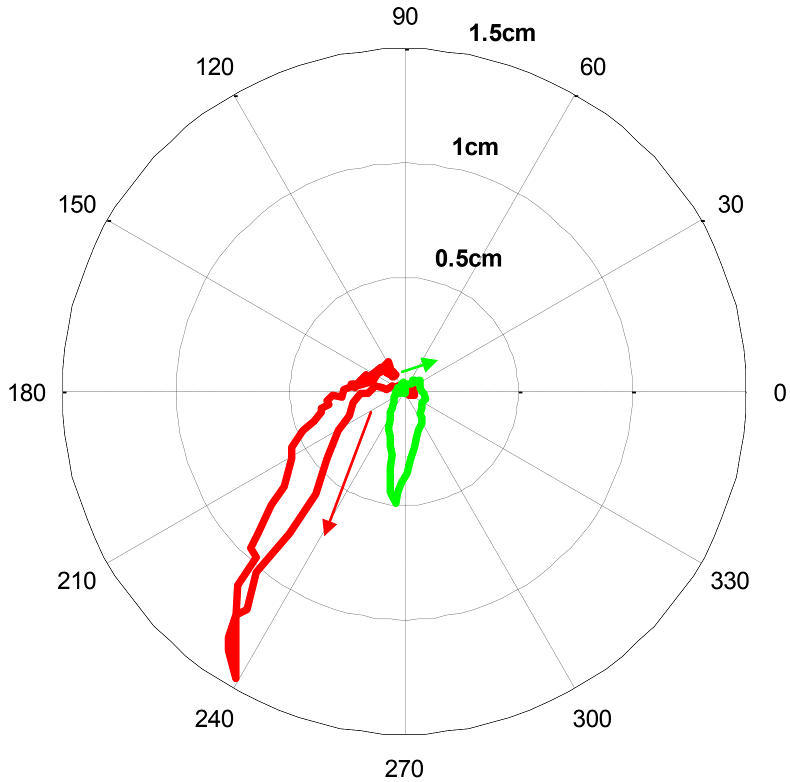


Figure 6.8: Comparison of the mean displacements (cm) and direction (degrees) of the ARA during a cough in standing continent (n = 16; green line) and SUI (n = 5; red line) women. The arrow in the ARA polar chart represents the initial direction of movement.

The ARA differences are more pronounced and statistically significant in the dorso-ventral displacement and angle of trajectory (Table 6.4). However correcting for unequal variances between the groups renders the resultant displacement almost statistically significant (P = 0.055).

There are also significant differences in maximum displacement values of the urethra in all directions between groups (Figure 6.9, Table 6.4). The urethra of continent group takes a more ventral trajectory, although the absolute angles are not significantly different between groups.

Table 6.4: Mean and SD of the maximum displacements and angle of ARA and urethral displacement during a cough in standing (mean ± SD, Unit: cm; Angle: degrees). (Continent n = 16 and SUI n = 5). (UV = Welch's correction applied for unequal variances)

	Dorsal Ventral	Cranial-Caudal	Resultant	Angle
ARA				
Continent	0.01 ± 0.29	-0.48 ± 0.31	0.55 ± 0.34	265 ± 25
SUI	-0.78 ± 0.40	-1.4 ± 1.2	1.6 ± 1.2	240 ± 10
P Value	**P<0.0001**	NS P = 0.076(UV)	NS P = 0.055(UV)	**P = 0.023**
Posterior				
Continent	-0.28 ± 0.25	-0.55 ± 0.31	0.65 ± 0.34	245 ± 25
SUI	-0.74 ± 0.38	-0.92 ± 0.41	1.2 ± 0.44	230 ± 15
P Value	**P = 0.002**	**P = 0.021**	**P = 0.003**	NS P = 0.14
Anterior				
Continent	-0.30 ± 0.26	-0.48 ± 0.18	0.59 ± 0.27	245 ± 20
SUI	-0.74 ± 0.38	-0.94 ± 0.44	1.2 ± 0.46	230 ± 15
P Value	**P = 0.004**	**P = 0.041**	**P = 0.0004**	**NS** P = 0.094

The posterior edge also moves slightly more than the anterior edge and both assume a co-linear path. In contrast, the trajectory of the urethra in the SUI group is more circular, and although the trajectory of the posterior edge is slightly wider than the trajectory of the anterior edge. The maximum displacements and overall angles are very similar.

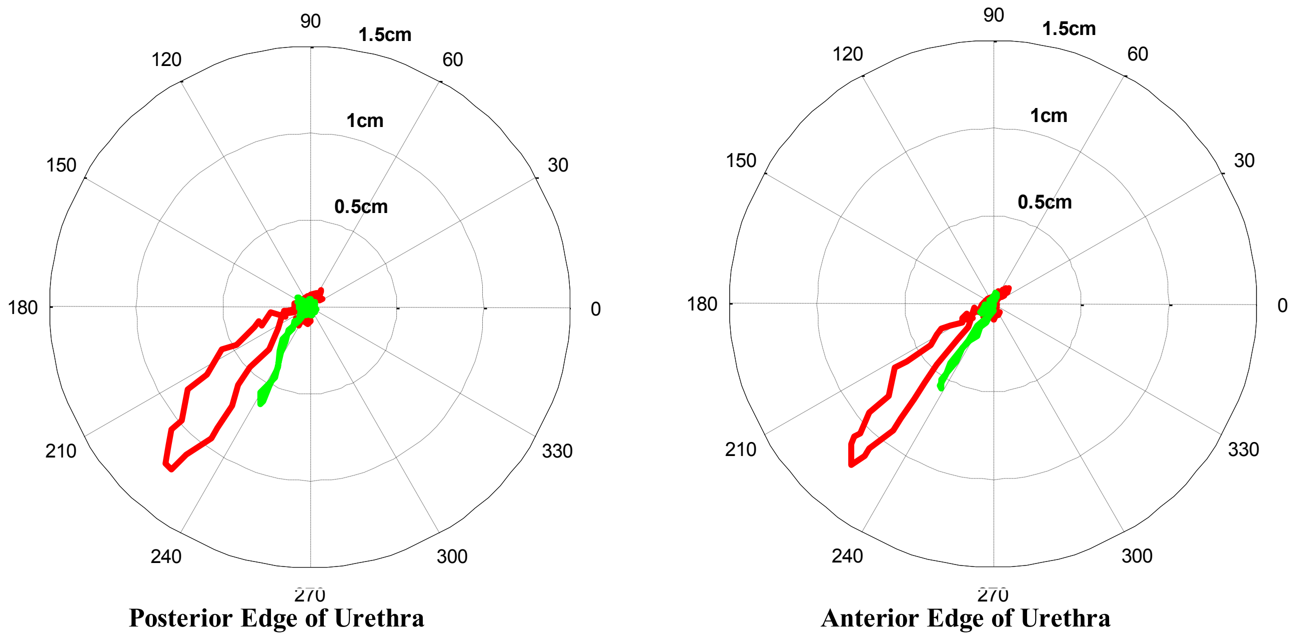


Figure 6.9: Comparison of the mean displacements (cm) and direction (degrees) of both edges of the urethra during a cough in standing continent (n = 16; green line) and SUI (n = 5; red line) women. Notice the co-linear path of the urethra of continent women compared with the more convoluted trajectory of the urethra in the SUI group.

6.5.6 Standing Velocity: During a cough in standing, the relative duration of movement and the maximum values of velocity are significantly different, although less comprehensively so than in supine (Table 6.5, Figure 6.9). The ARA of the continent group moves at a different rate and direction than the urethra whereas in the SUI group, the tissues move at a comparable velocity.

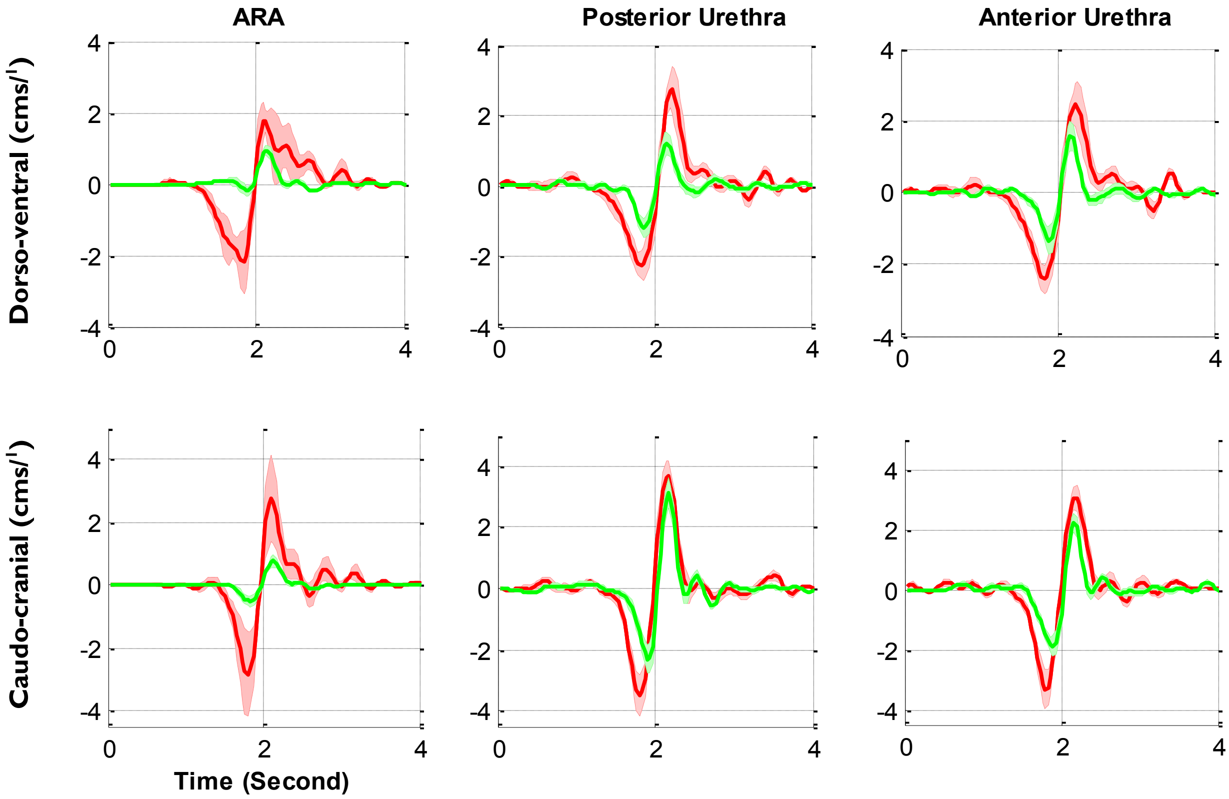


Figure 6.9: Comparison of the average velocities of the ARA, and both edges of the urethra during a cough in standing continent (n = 16; green line) and SUI (n = 5; red line) women. The shaded area represents the Standard Error (SE).

The ARA of the SUI group initially moves with up to six times the maximum dorso-ventral velocity of the continent group away from the SP, in comparison to the small ventral velocity of the continent group. Caudally, the SUI group moves with up to twice the velocity of the continent group. The continent group rebounds with an increased velocity in both the cranial and dorsal directions, whereas there is a tendency for the rebound velocities to be similar or less than the initial velocities in the SUI group.

The urethras of both groups move dorso-caudally, although the absolute angles are different and the velocity of the SUI group is at least one and a half times the maximum velocity of the continent group. The two edges of the urethra in the SUI group behave very similarly to each other, whereas the posterior edge in the continent group moves with a slower velocity than the anterior edge in a dorso-ventral direction, and the anterior edge moves slower in a caudo-cranial direction.

Table 6.5: Mean and SD of the maximum velocity of the ARA and urethra in standing during a cough before and after the synchronisation point (Mean ± SD, Unit: cm s^{-1}).

	Dorsal-Ventral		**Caudal-Cranial**	
ARA	**Before**	**After**	**Before**	**After**
Continent	0.076 ± 0.61	1.5 ± 1.0	-1.8 ± 1.8	2.4 ± 1.2
SUI	-2.6 ± 0.51	2.3 ± 0.57	-3.6 ± 1.6	3.1 ± 1.3
P Value	**P<0.0001**	**NS** P = 0.056	**P = 0.029**	**NS** P = 0.12
Posterior Urethra				
Continent	-1.7 ± 1.1	2.0 ± 1.2	-3.2 ± 1.6	3.6 ± 2.2
SUI	-3.2 ± 0.94	3.3 ± 2.1	-4.1 ± 2.3	4.3 ± 1.9
P Value	**P = 0.007**	**P = 0.044**	**NS** P = 0.15	**NS** P = 0.28
Anterior Urethra				
Continent	-2.0 ± 1.3	2.2 ± 1.5	-2.7 ± 0.86	2.7 ± 1.3
SUI	-3.2 ± 1.1	3.3 ± 2.1	-4.3 ± 2.3	4.3 ± 1.2
P Value	**P = 0.034**	**NS** P = 0.097	**NS** P = 0.10	**P = 0.02**

(Continent n = 16 and SUI n = 5). (UV = Welch's correction applied for unequal variances)

6.5.7 Standing Acceleration:

When the acceleration of each structure is directly compared between groups, we observe once more that although there is a tendency for the accelerations to be larger in the SUI group, in general the magnitudes of the maximum accelerations between groups are more similar than the velocities and displacements (Table 6.6). Significant differences were found for the initial cranio-ventral acceleration of the ARA and ventral acceleration of the posterior edge of the urethra and significant differences are almost reached for the urethra in the dorsal direction.

Table 6.6: Mean and SD of the maximum acceleration of the ARA and urethra in standing during a cough (Mean ± SD, Unit: cm s^{-2}) (Continent n = 16 and SUI n = 5).

	Ventral	**Dorsal**	**Cranial**	**Caudal**
ARA				
Continent	14 ± 9.5	-15 ± 12	24 ± 15	-20 ± 12
SUI	37 ± 20	-36 ± 27	41 ± 18	-38 ± 33
P Value	**P = 0.037** (UV)	NS P = 0.086	**P = 0.019**	NS P = 0.15
Posterior Urethra				
Continent	24 ± 15	-21 ± 11	44 ± 26	-35 ± 21
SUI	39± 15	-30 ± 11	46 ± 19	-34 ± 15
P Value	**P = 0.029**	NS P = 0.061	NS (P = 0.44)	NS (P = 0.48)
Anterior Urethra				
Continent	27 ± 19	-20 ± 13	34 ± 15	-26 ± 11
SUI	39 ± 15	-30 ± 11	46 ± 19	-34 ± 16
P Value	**NS (**P = 0.094)	NS P = 0.064	NS (P = 0.079)	NS (P = 0.10)

(UV = Welch's correction applied for unequal variances)

However the inconsistency of the accelerating forces in the SUI group is highlighted when we compare the effect of a change in posture within groups (Figure 6.10). Compared to the consistent and co-linear direction of the acceleration of the urethra in the continent group, the SUI group not only has a larger component transverse to the main direction of motion, but the net acceleration forces also vary significantly depending on the position

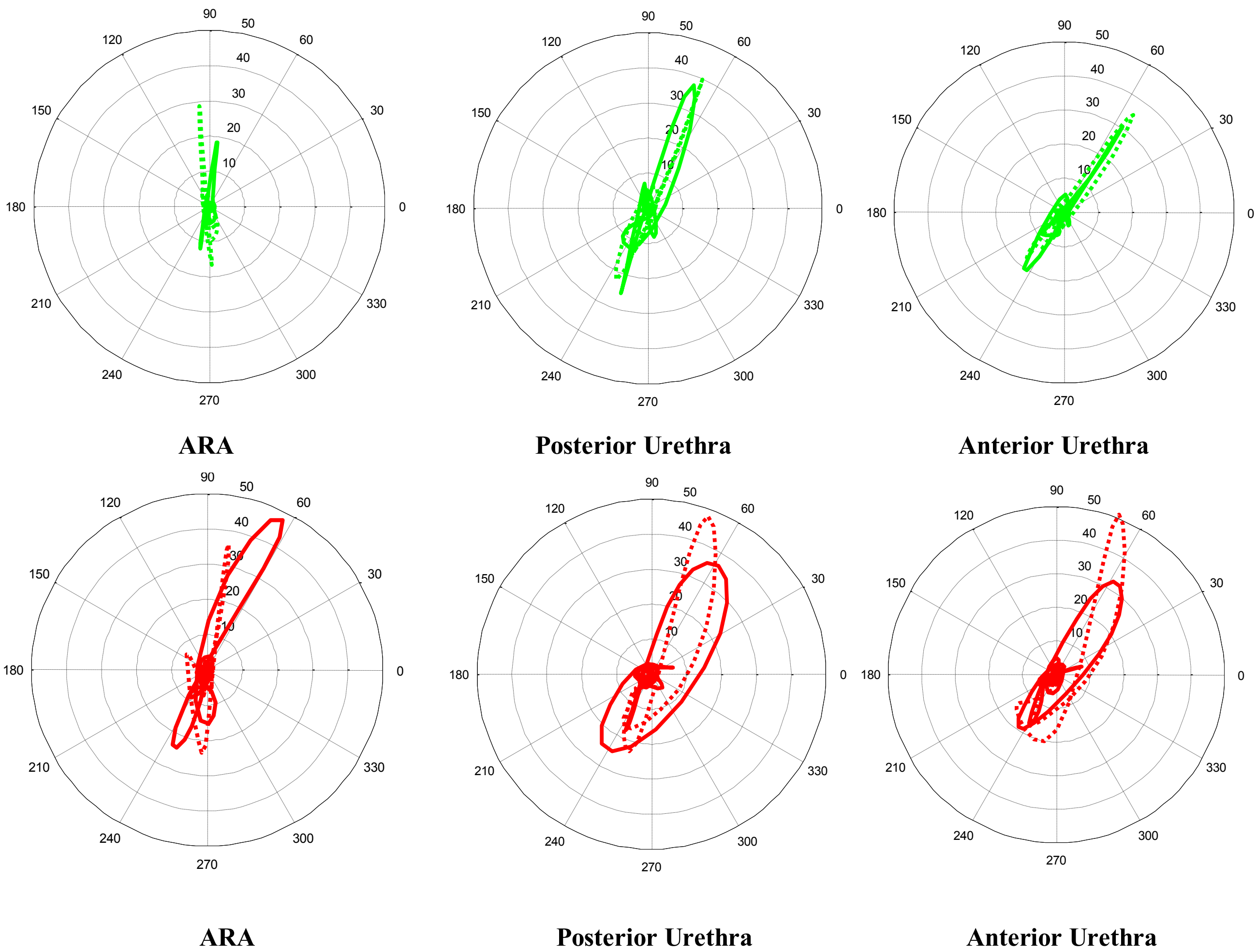


Figure 6.10: Comparison of the mean acceleration of the ARA, and both edges of the urethra during a cough in supine and standing: (n = 23; dotted green line continent supine; n = 16; solid green line continent standing; n = 9; dotted red line SUI supine; n = 5; solid red line SUI standing)

6.6 Discussion:

TP ultrasound imaging combined with IPM is able to discriminate between those individuals with SUI and those who are continent, and has provided novel insight into the dynamic function of the PF during a cough. The next section discusses the dynamic nature of the PFM and the effect upon the urethra.

6.6.1 Direction of PFM support during a cough:

We hypothesized that the PFMs, in terms of their timing and direction of contraction, would play an important role in maintaining continence. During a cough the PFM of continent women actively shorten, as indicated the reduction in distance between the ARA and SP and the initial direction of displacement, velocity and acceleration of the ARA. The implication of this observation is that in the continent group either there is an anticipatory PFM contraction or that the restoring forces of the PFM respond quickly to prevent any dorsal displacement caused by the rise in IAP during a cough. In SUI women the muscle is lengthening indicated by the increase in distance between the ARA and SP.

Active shortening of the PFM would also produce compression of the tissues, stiffening the PF and providing external support to the urethra, acting like a brake to reduce the velocity and displacement of the urethra and PF during a cough. This current study therefore provides evidence for and supports the hammock hypothesis first proposed by Delancey (DeLancey, 1994) . In addition, as the PFM contract simultaneously with the diaphragm and abdominal wall muscles to build abdominal pressure (Hodges *et al.*, 2007), the PFM contraction in the asymptomatic group may also help to tense the sub urethral fascial layer thereby enhancing urethral compression.

Ashton-Miller and DeLancey (Ashton-miller & Delancey, 2007;Hodges *et al.*, 2007) also theorized that if there were any interruption in the endopelvic fascia or if the PFM was damaged, the supportive layer under the urethra would be more compliant, so that closure of the urethral lumen would be delayed and stress incontinence was likely to occur. This current study has indicated that in the SUI group, the supportive layer under the urethra is elongated back and down during a cough and is much more compliant than that of the continent PF. Consequentially, in the SUI group, the PFM stiffness is reduced, so that the PF and urethra are displaced more before the restoring forces are sufficient to bring the tissue back to a state of equilibrium. Thus in the SUI the PF is like a saggy passive trampoline; once the tissues have been exposed to this downward stretch they rebound with a greater velocity.

6.6.2 Urethral displacement, velocity and acceleration:

During a cough, the urethra in both groups is displaced in a dorso-caudal direction, although in asymptomatic volunteers, the urethra is displaced less than half the distance with a smaller velocity. This implies that in the continent group, in addition to a stiffer PF to support the urethra, the fascial attachments of the urethra are stronger. Any tear or break in the continuity of the fascia will limit the external support of the urethra, therefore contributing to greater displacement. The increased likelihood of fascial disturbances in the SUI group is illustrated by the fact that the anterior edge of the urethra moves more than the posterior edge. In continent women, the anterior edge of the urethra moves less than the posterior edge which supports some anatomical studies (Mostwin, 1991) that indicate that the anterior edge is fixed to the posterior edge of the SP, whereas the posterior edge has less direct fascial attachment.

The combination of stronger urethral control due to intact fascia, and the presence of a PFM contraction in the continent group would account for the limitation of both the dorsal and caudal motion on the urethra during the cough and explains the linear path of displacement, velocity and acceleration. Although forces were not measured, the velocity and acceleration polar figures ((Figures 6.5, 6.7, 6.10) imply that the net forces upon the urethra in the continent group are principally along a single direction, whether the woman is in supine or standing and that the restoring forces in the transverse direction are balanced. In contrast, the convoluted path of the urethra in the SUI group suggest that there are uncontrolled forces on the urethra in the transverse direction as indicated by the “loops/kinks” in the polar plots of velocity and acceleration (Figures 6.5, 6.7, 6.10). Furthermore, from supine to standing, there is slightly greater acceleration and higher variability in the direction of acceleration, and therefore, the applied force.

Our maximum displacement for the continent group (Continent 8.4 ± 3.0 mm) is similar to Howard et al (Howard *et al.*, 2000) (8.2 ± 4.1mm) although the displacement of the urethra in our SUI group is significantly greater than the findings for their SUI group (SUI 20.8 ± 6.5mm compared to 13.8 ± 5.4 mm). Explanations of the differences between groups could be explained by sampling variations, or the accuracy of the data acquisition and methodology. The previous study (Howard *et al.*, 2000) was not able to account for the variance caused by identifying the SP, so it is likely that our measurement for the urethral displacement in the SUI group is more accurate. In practical terms, the potential measurement error caused by the requirement to accurately locate the SP and urethra is exacerbated in the SUI group. There is more movement of the transducer when an incontinent women coughs due to the lack of PFM contraction to limit the downward force and acceleration of the urogenital structures. More movement of the transducer will result in more apparent motion of the urogenital structures and SP on the ultrasound images. In addition due to the extra movement of the transducer, more frequent and greater episodes of short term out-of-plane rotation is likely to occur (Chapter 2, Section 2.11.2.3, and Chapter 5 Section 5.5).

6.7 Conclusions:

This study has, for the first time, characterised the automatic dynamic function of the PFM and accurately described the trajectory of the urethra during a cough. Significant differences exist in the behaviour of the PFM and urethra of women with SUI compared with continent controls. Normal PFM function during a cough produces timely compression of the PF and additional external support to the urethra, reducing the velocity and acceleration of the PF and urethra. In response to a cough the PF and urethra of SUI women therefore moves further, faster and for longer than asymptomatic women. The restraining forces do not increase as rapidly with displacement as those in continent women; evidence that the urethra and PF of asymptomatic women is stiffer than that of continent women.

No other imaging study has examined the effect of a cough in both supine and standing, and it is unclear whether the reduced displacement in standing found during this current study is due to a change in starting position of the urogenital structures. Therefore the next chapter investigates the relative position of the ARA and urethra in supine and standing and thoroughly explores the effect of a change in posture during a cough, including calculations of biomechanical strain.

7 Effect of a Change in Posture on the Pelvic Floor

7.1 Introduction

The previous chapter indicated that during a cough, there was greater displacement of the urethra in supine compared to standing in both continent and stress urinary incontinent (SUI) women. The ano-rectal angle (ARA) was also displaced more in supine than standing in the continent group; however in the SUI group, there was greater displacement of the ARA in standing compared to supine. In order to comprehensively describe the effect of a change in posture on the pelvic floor (PF) and different manoeuvres, it is important to be able to calculate and compare the relative starting positions of the urethra and ARA in different postures.

One study to date has examined the influence of posture on the urethra during a Valsalva using transperineal (TP) ultrasound imaging in women with lower urinary tract symptoms (LUTS) (Dietz & Clarke, 2001a). They concluded that the position of the bladder neck at rest was higher in the supine compared to a standing position, and it descended further on Valsalva, to reach an almost identical final position. The reliability of the measure was not established.

This chapter measures and compares the starting position of the urogenital structures of both groups in supine and in standing relative to the symphysis pubis (SP). It then verifies the inter-observer reliability of the calculations and finally builds on the results obtained in the previous chapter to give an indication of the overall mechanism of PF function during a cough and the clinical and research implications of these findings.

7.2 Aims

7.2.1 To evaluate the position of the urethra and ARA relative to the symphysis pubis (SP) in supine and standing in both continent and Stress Urinary Incontinent (SUI) women.

7.2.2 To establish the inter-observer reliability of measuring the position of the urethra and ARA relative to the SP.

7.2.3 To describe the effect of a cough on the displacement of the urethra and ARA after the relative starting positions of the tissues are accounted for.

7.3 Methods

7.3.1 To establish the relative position of the urethra and ARA to the SP, the audio-visual image (AVI) files of twenty three (23) continent and nine (9) women in supine and sixteen (16) continent and five (5) women with SUI were evaluated in standing. Each subject had five separate AVI files in each postures making 265 AVI files available for analysis. Three single static positions at the beginning of the AVI files were defined using the segmentation methodology described in Chapter 4, Section 4.4:

1. The position of the anterior edge of the urethro-vesical junction (UVJ) (Figure 7.1, P1)
2. The point on the ano-rectal junction, at the most acute point, closest to the y axis (Figure 7.1, P3)
3. The posterior inferior margin of the SP (Figure 7.3, 0')

As in the Section 4.4, the position of the urethra and ARA was measured relative to the coordinate system fixed on the posterior inferior margin of the SP (Figure 7.3).

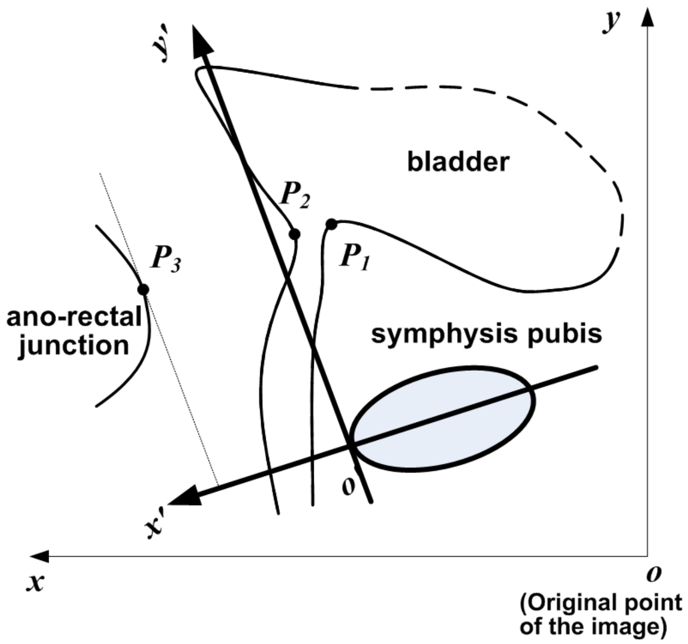


Figure 7.1: The coordinate system fixed on the posterior inferior margin of the symphysis pubis (x'-o'-y'). P1, P2 and P3 represent positions on the anterior and posterior edge of the urethra at the urethra-vesical junction (UVJ) and ARA respectively.

The average position of the urethra and ARA for each subject at rest was then calculated from the 5 AVI files in supine and standing. The relative position of the urethra and ARA in the continent and SUI groups were then compared and presented. Statistical comparisons using two-tailed unpaired T-tests, were performed to evaluate the mean values and standard deviation (+SD) and level of significant differences of the position of the urethra and ARA between the two groups.

7.3.2 In order to have greater confidence in interpretation of the outcome, the inter-observer reliability was established. Two independent observers (RLJ and QP) evaluated the static positions of the ARA, SP and urethra at rest in the same one hundred AVI files from five continent and five SUI women in both supine and standing. Both were blinded to each other's results.

The Standard Error of Measurement (SEM) was calculated for the averaged urethral and ARA position relative to the SP at rest, as well as methods recommended by Bland and Altman (Bland & Altman, 1986), and ICC with 95% CI. The same AVI files (targets) were rated by the same two judges, who were the only judges of interest, so a two way mixed effect ICC model (ICC 3,1) was used. Bland & Altman analysis was evaluated with GraphPad Prism 5 and ICC with SSPS 16.0 for Windows Graduate Pack.

7.4 Results

7.4.1 Inter-observer reliability:

The reliability for measurement of the position of the urethra is good to excellent in both groups (ICC 0.83 to 0.97), with SEM between 0.02 cm and 0.14 cm (Table 7.1a,b). Measurements for the position of the ARA are also good to excellent (ICC 0.77 to 0.94), SEM between 0.09 cm and 0.18 cm (Table 7.2).

Table 7.1a: Inter-observer reliability analysis of the dorso-ventral position of the urethra. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, SE= Standard Error SD_{diff} = Standard Deviation of difference. SEM=standard error of measurement.

	ICC		**Bland Altman**				
Inter-observer reliability	ICC	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Dorso-Ventral (X) Continent **SEM=0.14**	0.83(S) 0.91(A)	0.68→0.91 0.81→0.93	0.32	0.08	0.16→0.48	0.46	-0.58→1.20
Incontinent **SEM=0.08**	0.92(S) 0.96(A)	0.71→0.98 0.83→0.99	0.29	0.13	0.01→0.58	0.41	-0.50→1.09
Both groups **SEM=0.12**	0.87(S) 0.93(A)	0.78→0.93 0.87→0.96	0.31	0.07	0.18→0.45	0.44	-0.56→1.18

Table 7.1b: Inter-observer reliability analysis of the caudo-cranial position of the urethra. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, SE= Standard Error SD_{diff} = Standard Deviation of difference. SEM=standard error of measurement.

	ICC		**Bland Altman**				
Inter-observer reliability	ICC	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Caudo-Cranial (Y)							
Continent **SEM=0.02**	0.95(S) 0.97(A)	0.89→0.92 0.94→0.99	0.04	0.04	-0.06→0.13	0.13	-0.50→1.09
Incontinent **SEM=0.06**	0.92(S) 0.96(A)	0.72→0.98 0.84→0.99	0.02	0.07	-0.14→0.18	0.32	-0.60→0.63
Both groups **SEM=0.03**	0.94(S) 0.97(A)	0.89→0.97 0.94→0.98	0.06	0.03	0.004→0.12	0.19	-0.31→0.43

Table 7.2: Inter-observer reliability analysis of the position of the ARA. Intraclass correlation coefficient (ICC); (S)= single measures (A) =average measures: (L.O.A) = limits of agreement. = difference, SE= Standard Error SD_{diff} = Standard Deviation of difference. SEM=standard error of measurement.

	ICC		**Bland Altman**				
Inter-observer reliability	ICC	95% CI	$\bar{d}$ (cm)	SE of $\bar{d}$ (cm)	95% CI for $\bar{d}$ (cm)	SD_{diff} (cm)	95% LOA
Dorso-Ventral (X)							
Continent **SEM=0.18**	0.79(S) 0.88(A)	0.61→0.89 0.76→0.94	0.23	0.09	0.04→0.42	0.54	-0.84→1.30
Incontinent **SEM=0.14**	0.78(S) 0.86(A)	0.29→0.93 0.45→0.97	0.01	0.12	-0.26→0.28	0.38	-0.74→0.76
Both groups **SEM=0.18**	0.78(S) 0.88(A)	0.63→0.78 0.78→0.93	0.18	0.08	-0.21→0.34	0.52	-0.84→1.20
Caudo-Cranial (Y)							
Continent **SEM=0.09**	0.88(S) 0.94(A)	0.75→0.94 0.86→0.97	0.03	0.07	-0.12→0.18	0.37	-0.69→0.75
Incontinent **SEM=0.14**	0.77(S) 0.87(A)	0.30→0.93 0.47→0.96	0.01	0.12	-0.29→0.28	0.40	-0.79→0.78
Both groups **SEM=0.10**	0.86(S) 0.93(A)	0.75→0.93 0.85→0.96	0.02	0.06	-0.11→0.15	0.37	-0.71→0.75

7.4.2 The effect of a change in posture:

Relative to the SP, the starting positions of the urogenital tissues in the continent group are more cranio-ventrally placed than those of the SUI group (Figure 7.2). In both groups, the urethra drops in a caudo-dorsal and the ARA in a ventro-caudal direction when a woman stands up from supine. During a cough, the ARA of continent women moves towards the urethra both in supine and standing, however the ARA and urethra of the SUI group are displaced in approximately the same dorso-caudal direction. In both groups, during a cough, the position of maximum displacement of the urethra is significantly more dorso-caudal in standing compared to supine, as is the ARA of the SUI group. The ARA of the continent group whilst having more caudal displacement assumes a slightly more ventral trajectory in standing.

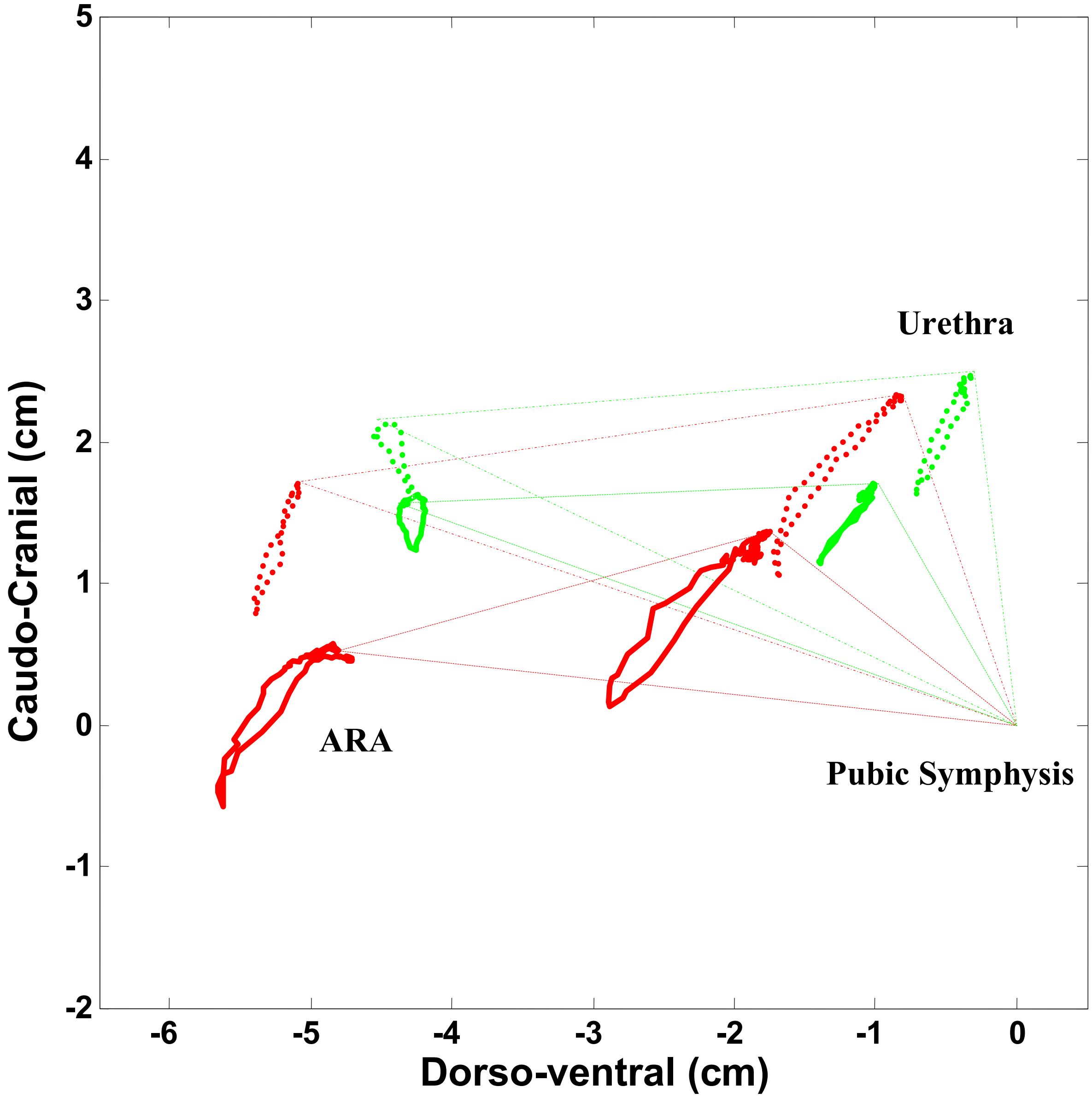


Figure 7.2: The relative starting positions and average trajectories of the urethra and ARA during a cough in supine and standing: (n = 23; dotted green line continent supine; n = 16; solid green line continent standing; n=9; dotted red line SUI supine; n=5; solid red line SUI standing).

The relative change in position for the urethra reaches statistical significance in both groups, whereas the ARA only reaches statistical significance in the SUI group, and only in the caudal direction (Table 7.3).

Table 7.3: Comparison of the position of the UVJ and ARA (measured from the symphysis pubis) for supine and standing. (Mean ± SD, Unit: cm) (n = 23; continent supine; n = 16; continent standing; n=9; SUI supine; n=5; SUI standing).

	Dorso-Ventral		Caudo-Cranial	
	Continent	**SUI**	**Continent**	**SUI**
Urethra				
Supine	-0.30 ± 0.65	-0.80 ± 1.3	2.5 ± 0.33	2.3 ± 1.2
Standing	-0.98 ± 0.44	-1.8 ± 1.1	1.7 ± 0.39	1.4 ± 0.78
P Value	**P = 0.007**	**P = 0.007**	**P = 0.002**	**P = 0.022**
ARA				
Supine	-4.5 ± 0.79	-5.1 ± 0.51	2.2 ± 0.67	1.7 ± 1.5
Standing	-4.4 ± 0.82	-4.8 ± 0.78	1.6 ± 0.85	0.53 ± 1.7
P Value	NS P = 0.350	NS P = 0.319	NS P = 0.078	**P = 0.016**

Figure 7.3 shows the mean distance between the respective points on the urogenital structures. During a cough, the ARA and urethra move further away from the reference point on the SP in the SUI group in standing (red solid line); whereas in supine, and in both positions in the continent group, the distances shorten or stay the same.

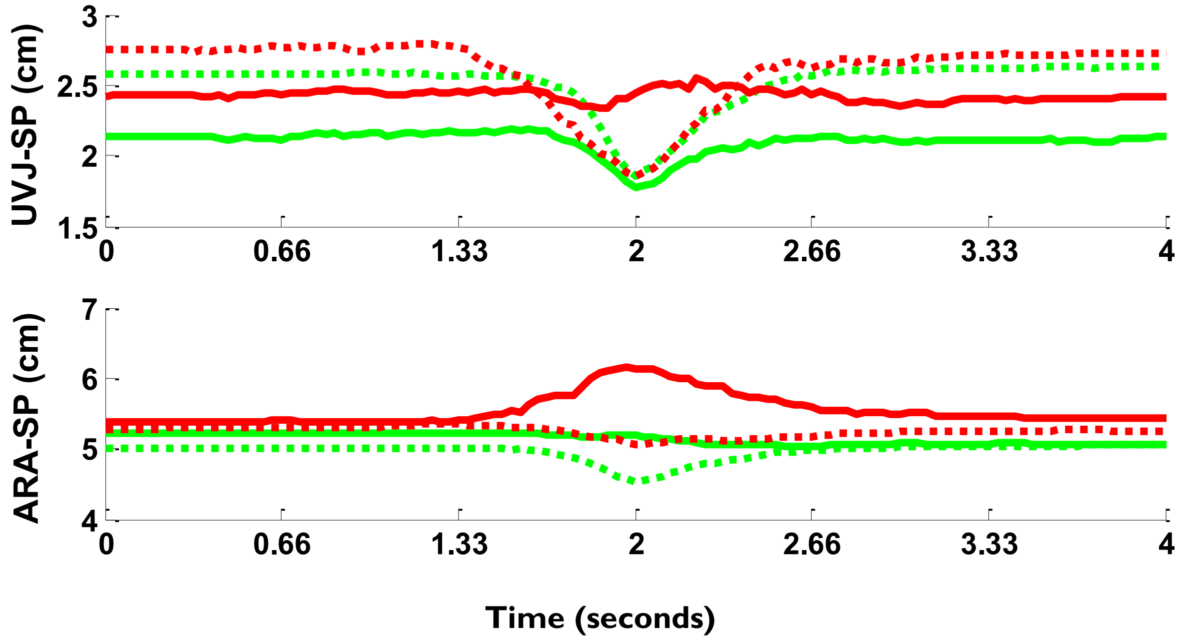


Figure 7.3: Mean length change between reference points of the UVJ, the SP and ARA during a cough in supine and standing: (n = 23; dotted green line continent supine; n = 16; solid green line continent standing; n = 9; dotted red line SUI supine; n = 5; solid red line SUI standing)

In the SUI group (the red solid and dotted line, Figure 7.4); the angle between the SP, urethra and the ARA attains the same degree at the maximum caudal position of the cough (at t= 2seconds), irrespective of the starting position. In the continent group (green solid and dotted lines), there is less angle change in supine than in standing.

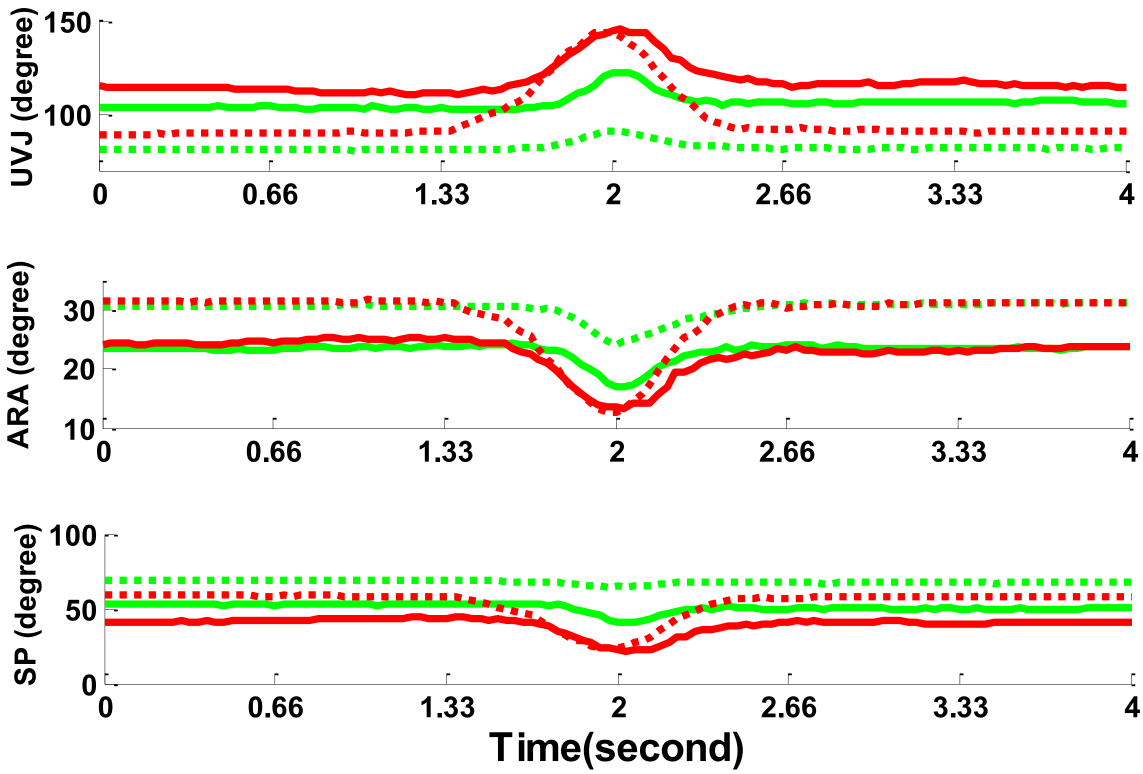


Figure 7.4: Angle change between reference points of the UVJ, the SP and ARA during a cough in supine and standing: (n = 23; dotted green line continent supine; n = 16; solid green line continent standing; n = 9; dotted red line SUI supine; n = 5; solid red line SUI standing)

Assuming that the PFM is aligned parallel to the plane of the image, and deformation occurs along the defined attachment points, the strain on the PF during a cough can be calculated in the various positions and groups (Rahmanian *et al.*, 2008) (Appendix 5c, algorithms). When strain is defined as the extent of deformation relative to its original condition; that is the ratio of the change in length to the original length, the maximum amount of strain of the PF of SUI women in supine reaches the maximum strain of continent women in standing (Table 7.4, Figure 7.5). The base of the PF of SUI women in standing is exposed to tensile (positive) strain, whereas the PF of the continent women and the incontinent women in supine are exposed to compressive (negative) strain.

Table 7.4: Maximum strain on the Pelvic Floor during a cough (Mean ± SD; Unit cm/cm)

	Maximum Strain	
Position	Continent	SUI
Supine	-0.088 ± 0.007	-0.041 ± 0.002
Standing	-0.045 ± 0.003	0.10 ± 0.04

(n = 23; continent supine; n = 16; continent standing; n=9; SUI supine; n=5; SUI standing).

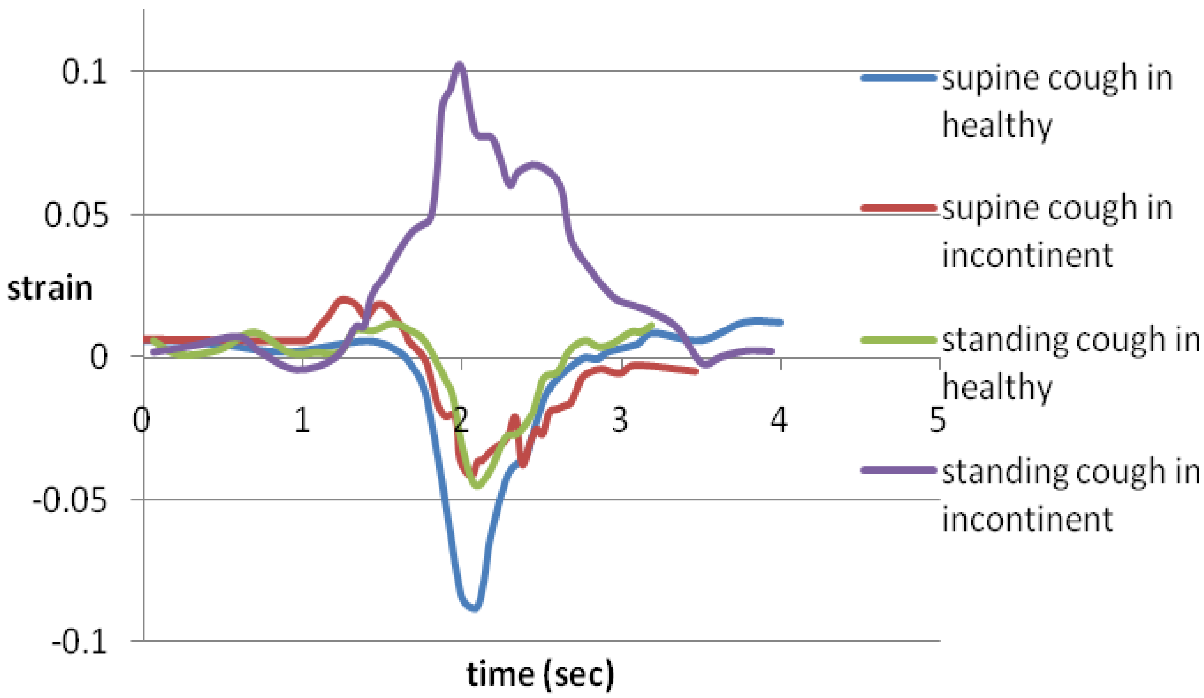


Figure 7.5: Muscle strain over time (Unit cm/cm) in continent and SUI women in supine and standing (n = 23; blue line continent supine; n = 16; green line continent standing; n = 9; red line SUI supine; n = 5; purple line SUI standing)

Furthermore, the strain rate, or the rate of elongation of the tissues over time during a cough can also be calculated, indicating that women with SUI have a much larger (P < 0.001) maximum positive and negative strain rate than continent women (Figure 7.6, Table 7.5).

Table 7.5: Maximum strain rate (± SD) in healthy and SUI women during a cough in supine

Cough	**Strain Rate (strain/sec)**	**P value**
Healthy	-27.4 ± 0.5	< 0.0001
SUI	-199.2 ± 0.7	

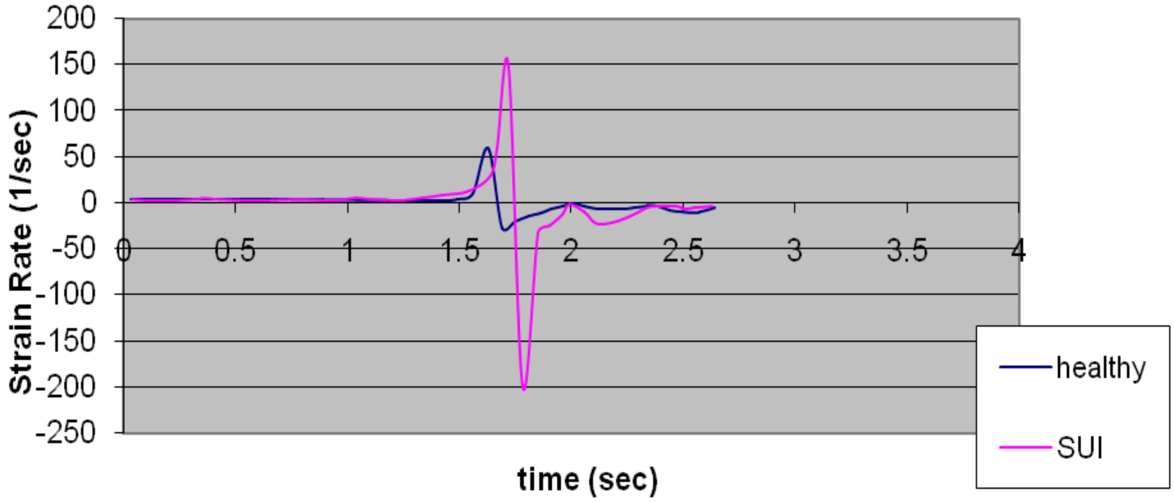


Figure 7.6: Strain rate over time in continent and SUI women during a cough in supine. (n = 23; blue line continent; n = 9; pink line SUI)

7.5 Discussion

The novel image processing methods have been able to provide an accurate, comprehensive overview of the relative starting positions of the PF structures within and between groups, and the effect of changing position on the trajectory of the urogenital structures during a cough. The following section discusses these findings, building upon the results of Chapter 6 to provide further insight into the function of the PF during a cough and the implications for rehabilitation in SUI women.

7.5.1 Reliability

Image processing methods to evaluate the relative position of the ARA and urethra in supine and standing in continent and SUI women had good to excellent inter-observer reliability, allowing confident interpretation of the change in position of the pelvic structures in this study. However, due to the limited number of women, particularly within the SUI group in standing, caution is advised regarding the generalisability of the results.

7.5.2 Change of Posture

The effect of posture, from supine to standing, on the location of the urethra and ARA relative to the pubic bone was studied and the results are consistent with two other studies measuring the effect of posture on the position of the urethra with TP ultrasound which indicated that the urethra drops in a caudal position from supine to standing (Dietz & Clarke, 2001a).

The visualisation of the relative starting positions from supine to standing, within and between groups, assists in the understanding of why a change in position from supine to standing results in less displacement of the urethra during a cough. Although from a zero reference point there was greater displacement of the urethra in supine compared to standing in both continent and SUI women, (Chapter 6, Tables 6.1, 6.4); once the starting position is accounted for, the maximum dorso-caudal displacement of the urethra in standing is significantly greater than in supine (Figure 7.2).

In the continent group, there was less change in the starting position of the ARA than the urethral position, most likely due to the greater connective tissue and muscular support of this structure. Unlike the urethra which is supported passively by connective tissue restraints, a change in position of the ARA will represent both active muscular changes due to the presence or absence of a PFM contraction, as well as the passive tissue restraints. Possibly the starting position of the ARA in the continent group did not descend so far due to the greater increase in activity of the PFM in continent women in response to the change in posture. The effect of a change in posture on vaginal closure force was evaluated in asymptomatic women (Morgan *et al.*, 2005). They concluded that vaginal closure force increased in standing because of higher intra-abdominal pressure (IAP) and greater resistance in the PFM. This supports EMG studies that indicate greater PFM activity in standing compared to the supine position (Morgan *et al.*, 2005;Smith *et al.*, 2007a;Hodges *et al.*, 2007).

Although from a zero reference point, in the continent group, the ARA was displaced more during a cough in supine than in standing (Chapter 6, Tables 6.1, 6.4); accounting for the relative starting positions, the overall caudal displacement was greater in standing.

In the SUI group, there was a significant drop in position of the ARA. The implication is that perhaps the PFM in SUI women may not have an automatic increase in activity from supine to standing, yet EMG studies suggest otherwise (Morgan *et al.*, 2005;Smith *et al.*, 2007a;Hodges *et al.*, 2007). From a zero reference point, the ARA in the SUI group was displaced more during a cough in standing than in supine (Figures 7.2, 7.3, 7.5 Table 7.3).

The dynamic quality of our study therefore was able to provide new anatomical and physiological rationale to explain the common clinical and researched observation that provocation of incontinence and prolapse is more frequent in standing than supine (Nguyen *et al.*, 2002;Norton & Baker, 1994). With reference to Figures 7.2 and 7.3 during a cough in the continent group in both postures, and the SUI group in supine, the overall distance between a point on the SP and the ARA decreased, whereas this same measurement increased during a cough in standing in SUI women. Strain calculations therefore indicated that in the continent group in supine and standing, and in the SUI in supine only, the strain was compressive, pushing the tissues together, rather than stretching them apart. In standing however, the PF of SUI women was exposed to a tensile strain.

The starting angles of the urethra and ARA, and the deformation throughout a cough, highlight the differences between continent and SUI groups. Firstly, in the SUI group, there is greater change during a cough, and secondly, irrespective of posture, the angles converge to the same degree. The change in urethral angle throughout the cough most likely represents the funnelling of the urethra observed under strain, described in previous cystourethrography and ultrasonic studies (Schaer *et al.*, 1995). In the SUI group our findings suggest that the urethral deformation reaches its elastic limit in both positions, most likely due to the combination of a lack of active and passive connective tissue restraints in the SUI group. In the control group, there is minimal angle change in supine, more deformation in standing, but overall much less than in the SUI group.

7.5.3 Clinical and research implications:

This study illustrates that forces external to the urethra are indeed important for continence function. The PFM of continent women automatically contracts and shortens during a cough, which supports the pelvic organs by reducing the length of the PF and displacing the pelvic viscera towards the pubic bone (Figures 6.2, 6.3, 6.8, 7.2, 7.3). The absence of similar support in the incontinent group means that the pelvic viscera are exposed to greater strain during coughing and potentially other activities that raise the IAP. Furthermore, connective tissue restraints within this SUI group, which maintain the location of the pelvic organs, will be elongated further.

The dynamic quality of our study was able to provide new anatomical and physiological rationale to explain the common clinical and researched observation that provocation of incontinence and prolapse are more frequent in standing than supine (Nguyen *et al.*, 2002;Norton & Baker, 1994). The cumulative effect over time of the strain on the PF, especially in standing, due to less PFM support may be additional reasons as to why incontinence increases with advancing age (Perucchini *et al.*, 2002a;Perucchini *et al.*, 2002b), and previously successful surgeries fail (Olsen *et al.*, 1997). Should surgical intervention improve continence function, yet the PFM still be dysfunctional, restoring appropriate PFM support could, theoretically, improve the longevity of the procedure. A further implication for rehabilitation of women with SUI is to ensure that PFM training is taught in both the supine and standing positions.

7.6 Conclusions

The image processing methods have been able to accurately describe novel characteristics of PFM and urethral function during a change in position from supine to standing.

The urethra and ARA of continent women are in a more cranio-ventral position in the pelvis than that of women with SUI, especially in a standing position. Studies describing displacement of PFM structures during manoeuvres in different positions need to account for the relative starting position, as although the displacement may appear greater (or smaller), the overall displacement will be affected by the initial starting position.

In SUI women, the PF is exposed to tensile strain during a cough in standing and provides an explanation of why women with SUI describe symptoms of leaking more frequently in standing compared to supine.

The last two chapters have emphasised that one distinctive difference between continent and SUI women during a cough was the presence of a well timed PFM contraction that supported the urethra. A common rehabilitation tool in the conservative treatment of women with SUI is a PFM contraction held prior to and throughout a cough "The Knack". The next chapter determines whether the image processing methodology is specific enough to be able to distinguish between a cough and the Knack and catalogues any differences in the response of the PF.

8 Effect of "The Knack" on the Pelvic Floor: Evaluated by Real Time Ultrasound and Image Processing Methods.

8.1 Introduction

Several randomised controlled trials (RCT) and systematic reviews have demonstrated that pelvic floor muscle (PFM) training in women with stress urinary incontinence (SUI) is more effective than untreated controls or other treatment modalities, with varying cure rates between 44% and 67% (Henalla *et al.*, 1988;Miller *et al.*, 1998;Morkved *et al.*, 2002;Dumoulin *et al.*, 2004b;Dumoulin & Hay-Smith, 2008). Successful conservative treatment has concentrated upon strength training of the PFM in addition to adding "The Knack" which is a PFM contraction prior to and during activities that increase intra-abdominal pressure (IAP) (Miller *et al.*, 1998).

The Knack is also known in the UK as counterbracing, or a voluntary PFM contraction in response to a specific situation (Dumoulin & Hay-Smith, 2008). It has been shown to be an effective treatment for selected older women with mild stress or mixed incontinence in a prospective, randomised, single-blind interventional study (Miller *et al.*, 1998). A more recent blinded RCT also indicated no significant difference between a programme using the Knack manoeuvre alone compared with the Knack plus PFM strengthening (Hay-Smith EJC. *et al.*, 2002).

Despite extensive investigation, in part due to the lack of suitable instrumentation, the mechanisms by which PFM training does or does not work are poorly understood (Bo, 2004). As discussed earlier (Chapter 2, Section 2.9), most PFM measurement tools have concentrated on the ability to measure strength of voluntary PFM contraction, whereas other qualities of PFM function may be at least as critical for effective treatment. Further complicating our understanding about how and why PFM training reduces urine leakage is the fact that many research studies that report an emphasis on strength training also imply that the Knack manoeuvre was taught at the same time (Cammu *et al.*, 1991;Bo & Talseth, 1996;Wyman *et al.*, 1998;Burgio *et al.*, 2003;Dumoulin & Hay-Smith, 2008).

In an attempt to understand the therapeutic mechanisms of the Knack, two studies have examined the Knack manoeuvre as a treatment approach alone, without concurrent strength training (Miller *et al.*, 2001;Miller *et al.*, 2008). These studies suggest that the Knack temporarily increases both the stiffness in the support of the urethra and pressure within the urethra, thereby resisting leakage during rises of IAP.

Yet there still remains only partial understanding of the how the Knack may work and why in a proportion of women it fails to show any reduction in leakage volume (Miller *et al.*, 2008). In their latest study(Miller *et al.*, 2008) , twenty percent of their study failed to show any reduction in leakage volume in comparison to a cough without any PFM pre-contraction and they suggested three plausible explanations as to why this may be the case:

1. The PFM and/or urethral striated muscle could be underdeveloped, injured, or atrophied to such an extent that it was not possible to perform an effective contraction, or contraction was possible but of insufficient strength;
2. The women may have required additional training to develop the co-ordination and skill necessary to produce an effective Knack manoeuvre during a cough;
3. A portion of the women may already employed the Knack manoeuvre, such that when asked to cough, were unable to refrain from contracting their PFM.

The reliable novel image processing methods (IPM) described in Chapter 4 and 5 allow the opportunity to visualise the whole sequence of the PFM and urethra during manoeuvres. IPM combined with transperineal (TP) ultrasound will be a very useful measurement tool in the future if it is specific enough to be able to distinguish the Knack from a cough, indicate whether a patient requires further skill training, or that the PFM contraction is ineffective.

This experimental chapter describes the mechanisms of PFM function during a Knack in continent and SUI women and the effect on the urethra. It then compares the results from the cough in Chapter 6 to determine the differences in the response of the pelvic floor (PF) to stress due to coughing and in the presence of pre-contraction or the Knack.

8.2 Aims

8.2.1 To gain greater understanding of the mechanisms of the Knack, describing the kinematic properties of the PF in continent and SUI women by measuring the displacement, velocity and acceleration of the ano-rectal angle (ARA) and the urethra.

8.2.2 To determine whether transperineal (TP) ultrasound combined with IPM is able to distinguish between a cough without a PFM contraction and the Knack.

8.3 Hypotheses

8.3.1 During the knack, there is less dorso-caudal displacement, velocity and acceleration of the urethra in continent women than in women with SUI.

8.3.2 In SUI women the displacement, velocity and acceleration of the urethra during the Knack is comparable to the properties of continent women coughing without the benefit a PFM pre-contraction.

8.4 Methods

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3.

Thirty three (33) female volunteers were asked to perform three consecutive Knack manoeuvres, with a 5 second rest in between each one with the transperineal (TP) ultrasound transducer in position, in supine and if time allowed in standing too. The ability to perform the Knack had been verified with digital palpation and instruction on how to perform the Knack was given with the command:

"Squeeze around the back passage, as if you were trying to prevent breaking wind (flatus); bring that feeling forward towards the urethra/pubic bone and then lift, as if you were elevating the PFM. Whilst holding this contraction, cough as hard as you can".

8.4.1 TP ultrasound, image processing methods and graph alignment:

Application of the ultrasound transducer (Section and 6.4.1); segmentation methodology for the urethra and relative position of the urogenital structures (Sections 4.4, 6.4.2 and 7.3.1); motion tracking algorithms for the symphysis pubis (SP) and ARA (Section 4.3, 6.4.2); have already been described. Graph alignment throughout is at the maximum caudal displacement.

8.4.2 Statistical analysis:

Comparisons within and between groups of the mean and Standard Error (SE) of the displacement, velocity and acceleration of the Knack in supine and standing, and between a cough and the Knack were calculated and presented graphically. Statistical comparisons between groups using one-tailed unpaired t-tests were performed to evaluate the mean values (±2SD) and level of significant differences of the displacement, velocity and acceleration components between the two groups. Where the variances were unequal, Welch's correction was applied, and a level of P < 0.05 was considered significant. GraphPad Prism version 5.01 for Windows was used for statistical analysis.

8.5 Results

The displacement of the urethra and ARA in twenty-three (23) continent women were analysed in supine, and sixteen (16) in standing. Nine (9) women with SUI were analysed in supine, five (5) in standing. ARA and urethral displacements were normally distributed in both the supine and standing positions.

The first section of the results will present comparisons between continent and SUI women performing the Knack, in supine, then in standing. Subsequently within group comparisons of a cough and the Knack will be analysed to indicate whether the IPM can distinguish the Knack from a cough. Finally, a cough in continent women will be compared to the Knack in SUI women, in order to gain greater understanding of the immediate benefits of the Knack as a rehabilitation tool.

8.5.1 Supine displacement:

All ARA and urethral displacements, velocities and accelerations were normally distributed. There were significant differences in both the direction and magnitude of displacement of the ARA and urethra during a Knack between groups (Table 8.1, Figures 8.1, 8.2, 8.3).

Table 8.1: Mean and SD of the maximum displacements of ARA and urethral displacement at the synchronisation point during the Knack in supine (mean ± SD, Unit: cm; Angle: degrees). (Continent n = 23 and SUI n = 9). (UV = Welch's correction applied for unequal variances)

	Dorso-ventral	**Cranial-Caudal**	**Resultant**	**Angle**
ARA				
Continent	0.43 ± 0.32	-0.24 ± 0.25	0.67 ± 0.25	330 ± 36
SUI	-0.02 ± 0.37	-0.69 ± 0.38	0.82 ± 0.36	280 ± 33
P Value	**P = 0.001**	**P = 0.0002**	**NS** P = 0.10	**P = 0.0009**
Posterior				
Continent	-0.16 ± 0.24	-0.40 ± 0.17	-0.51 ± 0.19	260 ± 34
SUI	-0.47 ± 0.17	-1.00 ± 0.14	-1.10 ± 0.12	240 ± 11
P Value	**P = 0.01**	**P < 0.0001**	**P < 0.0001**	**NS** P = 0.16 (UV)
Anterior				
Continent	-0.26 ± 0.34	-0.41 ± 0.28	-0.59 ± 0.34	250 ± 30
SUI	-0.41 ± 0.30	-1.10 ± 0.24	-1.20 ± 0.27	250 ± 17
P Value	**NS** P = 0.26	**P = 0.0002**	**P = 0.002**	**NS** P = 0.47

First the trajectory of the Knack in supine will be described, followed by comparisons between groups.

8.5.1.1 The trajectory of the ARA in continent women: During the initial voluntary PFM contraction component of the Knack [Figure 8.1 green arrow (a)], the ARA of continent women moved at a mean angle of 35 degrees for 0.65 cm. During the cough component [Figure 8.1 green arrow (b)] it was displaced in a predominately caudal direction, at a maximum angle of 330 ± 36 degrees to its maximum caudal position of 0.67 ± 0.25 cm, before returning to a position slightly more caudal than the original starting position [green arrow (c)].

8.5.1.2 The trajectory of the ARA in SUI women: During the initial voluntary PFM contraction component of the Knack [Figure 8.1 red arrow (a)], the ARA moved at a mean angle of 38 degrees for 0.4 cm before being displaced in a dorso-caudal direction, at a maximum angle of 280 ± 33 degrees for 0.82 ± 0.36 cm [Figure 8.1 red arrow (b)], before returning back to a position slightly more dorsal than the original starting position [red arrow (c)].

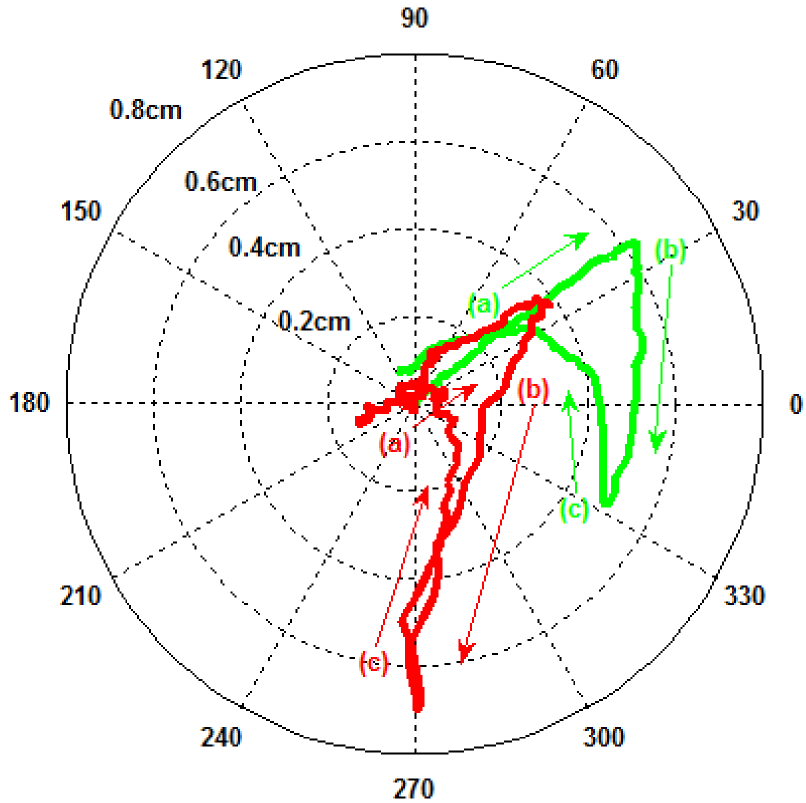
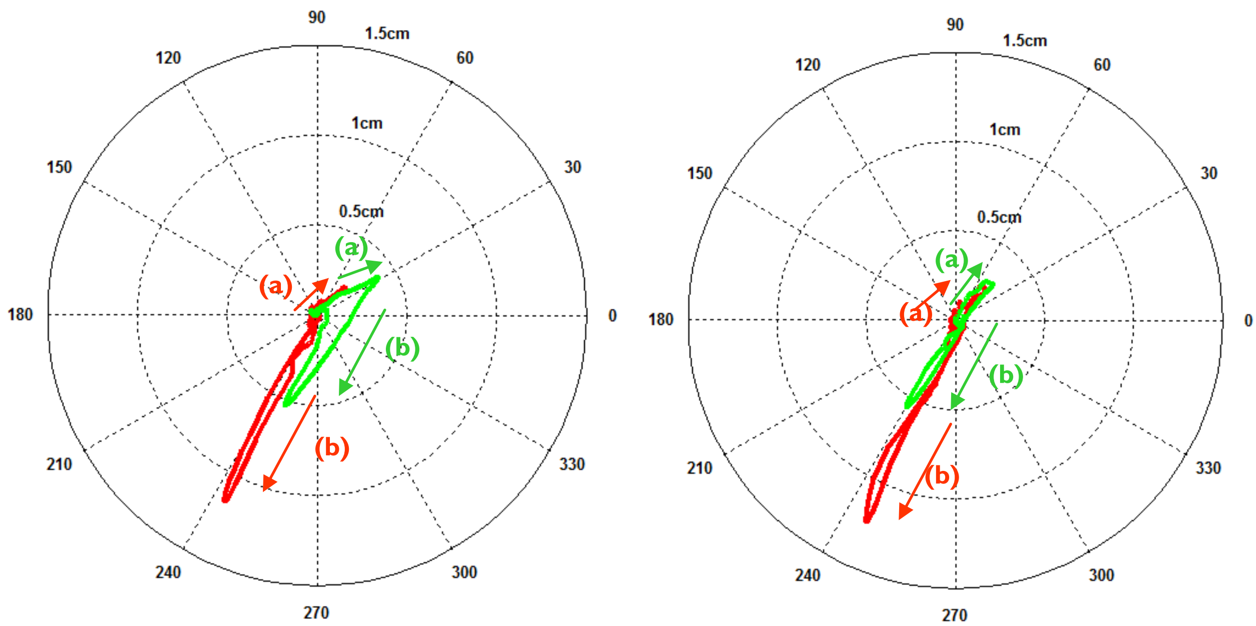


Figure 8.1: Comparison of the trajectory of the ARA during the Knack in supine continent (n = 23; green line) and SUI (ARA n = 9; red line) women. Arrow (a) represents the initial PFM component of the Knack; (b) the cough component and (c) the return to final resting position.

8.5.1.3 Urethral trajectory in continent women: During the PFM component of the Knack, the posterior edge of the urethra initially moved cranio-ventrally at a mean angle of 33 degrees for 0.40 cm, [Figure 8.2a green arrow (a)], before it was displaced 0.5

± 0.2 cm in a dorso-caudal direction at a maximum mean angle of 260 ± 34 degrees during the cough component [Figure 8.2a green arrow (b)]. There was less displacement of the anterior edge of the urethra during the PFM component than the posterior edge, initially moving cranio-ventrally at a mean angle of 44 degrees for 0.30 cm, before it was displaced 0.6 ± 0.3 cm in a dorso-caudal direction at a maximum mean angle of 250 ± 30 degrees (Figure 8.2b).

8.5.1.4 Urethral trajectory in SUI Women: The posterior edge moved cranio-ventrally at a mean angle of 43 degrees for 0.20 cm [Figure 8.2a red arrow (a)], before it was displaced 1.1 ± 0.1 cm in a dorso-caudal direction at a maximum mean angle of 240 ± 11 degrees [Figure 8.2a red arrow (b)]. The anterior edge moved slightly more than the posterior edge, moving cranio-ventrally at a mean angle of 49 degrees for 0.25 cm; before it was displaced 1.2 ± 0.3 cm in a dorso-caudal direction at a maximum mean angle of 250 ± 17 degrees (Figure 8.2b).



Post edge urethra (a) Ant edge urethra (b)

Figure 8.2: Comparison of the mean displacements of both edges of the urethra during the Knack in supine continent (n = 11; green line) and SUI (n = 5; red line) women. Arrow (a) represents the initial PFM component of the Knack; (b) the cough component.

8.5.1.5 Dorso-ventral and caudo-cranial displacements:

Decomposing the trajectory into the dorso-ventral and cranio-caudal components emphasised the direction specific differences between groups during the Knack (Table 8.1,

Figure 8.3). In the initial PFM component of the Knack, the ARA of the continent group had significantly more ventral displacement than that of the SUI group (P=0.02). Unlike the ARA of the SUI group, the continent group was able to maintain most of its ventral displacement throughout the cough part of the manoeuvre (Figure 8.1, 8.3).

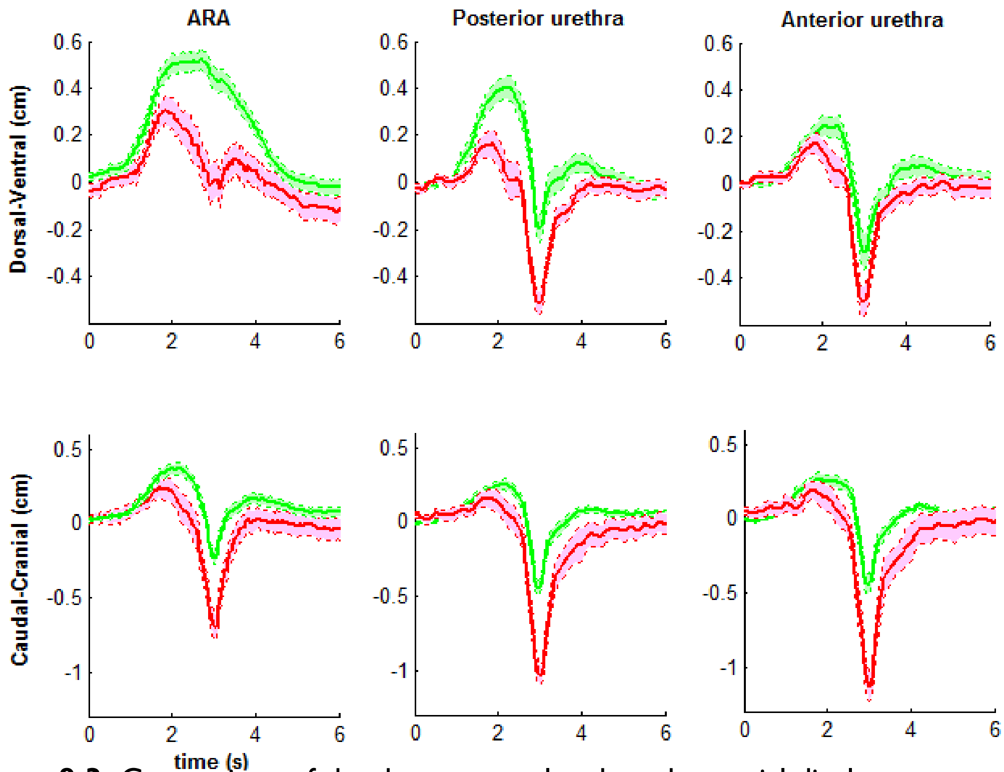


Figure 8.3: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra during the Knack in supine continent (ARA n = 23; urethra n = 11; green line) and SUI (ARA n = 9; urethra n = 5; red line) women. The shaded area represents the SE.

Cranio-caudally the overall displacement pattern was more similar but there were significant differences in magnitude of displacement. Through the cough part of the Knack, both groups lost much of the caudal displacement created by the PFM component of the Knack, although the ARA of the SUI group descended over twice the distance of the ARA of the continent group (Table 8.1).

There was also over twice as much displacement of the urethra in the SUI groups compared to the continent group although the overall urethral angles of displacement were similar (Table 8.1). In addition, there was significantly more ($P< 0.05$) initial ventral displacement of the posterior edge of the urethra in the continent (0.42 ± 0.21cm) than in the SUI group (0.26 ± 0.14cm).

8.5.2 Supine velocity:

In SUI women, the maximum caudo-cranial velocities of the ARA and urethra were significantly greater than that of the continent group (Table 8.2, Figure 8.4).

Table 8.2: Mean and SD of the maximum velocity of the ARA and urethra in supine during the Knack (Mean ± SD, Unit: cm s^{-1}). (ARA; Continent n = 23 and SUI n = 9: Urethra; Continent n = 11 and SUI n = 5).

ARA	**Dorsal**	**Ventral**	**Caudal**	**Cranial**
Continent	-1.5 ± 0.48	1.8 ± 0.80	-2.2 ± 0.77	2.1 ± 0.55
SUI	-1.8 ± 0.69	1.8 ± 0.74	-2.9 ± 0.47	2.7 ± 1.0
P Value	**NS** P = 0.097	**NS** P = 0.44	**P = 0.009**	**P=0.049 (UV)**
Posterior				
Continent	-2.1 ± 0.79	1.8 ± 0.65	-2.5 ± 1.0	2.3 ± 0.78
SUI	-2.3 ± 0.76	1.9 ± 0.58	-3.7 ± 0.89	3.1 ± 0.81
P Value	**NS** P = 0.32	**NS** P = 0.42	**P = 0.019**	**P = 0.035**
Anterior				
Continent	-2.1 ± 0.99	1.8 ± 0.72	-2.7 ± 0.87	2.6 ± 0.82
SUI	-2.5 ± 0.75	1.9 ± 0.90	-3.9 ± 1.3	3.7 ± 1.4
P Value	**NS** P = 0.23	**NS** P = 0.37	**P = 0.022**	**P = 0.030**

Although the maximum velocities were more similar in the dorso-ventral direction; in the time periods 0.5 seconds before and after the synchronisation point at the maximum caudal displacement; the ARA of the continent group moved with a significantly slower velocity in the dorso-ventral direction ($P < 0.05$). The wave form of ventral velocity of the posterior edge of the urethra also appeared more consistent in the continent group (Figure 8.4).

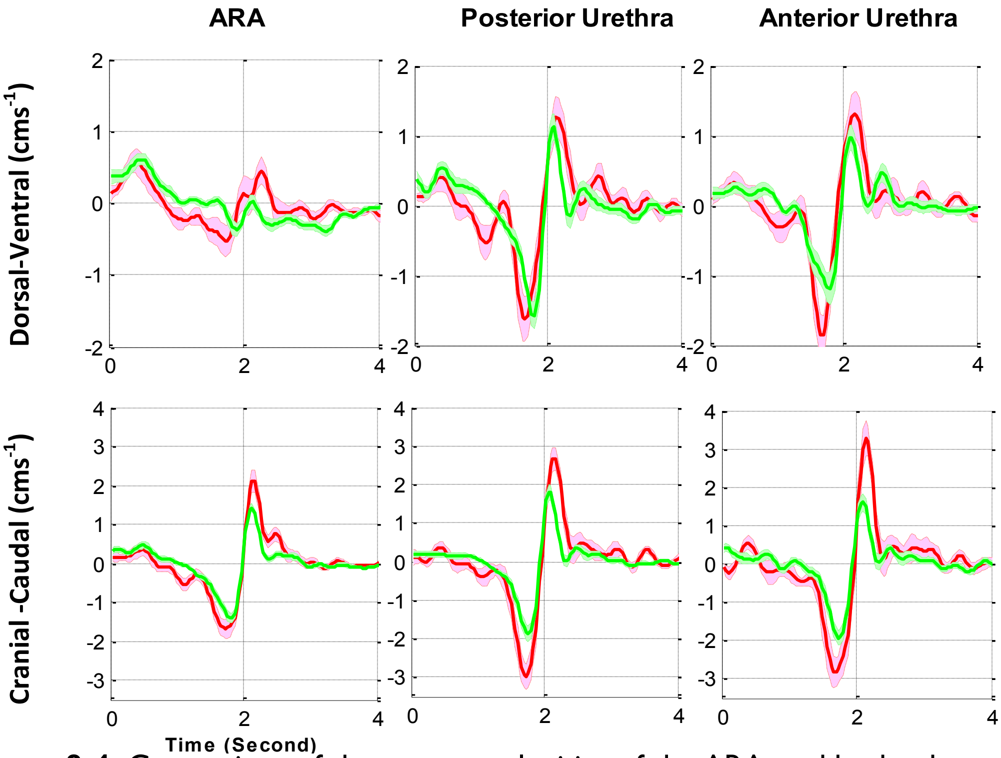


Figure 8.4: Comparison of the average velocities of the ARA, and both edges of the urethra during the Knack in supine continent (ARA n = 23; urethra n = 11; green line) and SUI (ARA n = 9; urethra n = 5; red line) women. The shaded area represents the SE.

8.5.3 Supine acceleration: There was a tendency for the accelerations to be larger in the SUI group particularly in the caudo-cranial direction, although the magnitudes of the maximum accelerations between groups were more similar than the velocities and displacements (Figure 8.5, Table 8.3). As with the velocities, in the dorsal ventral direction, the ARA and urethra of continent and SUI women behaved in a more similar fashion, yet the polar plots (Figure 8.5) emphasised the less controlled transverse accelerating forces observed in the SUI group.

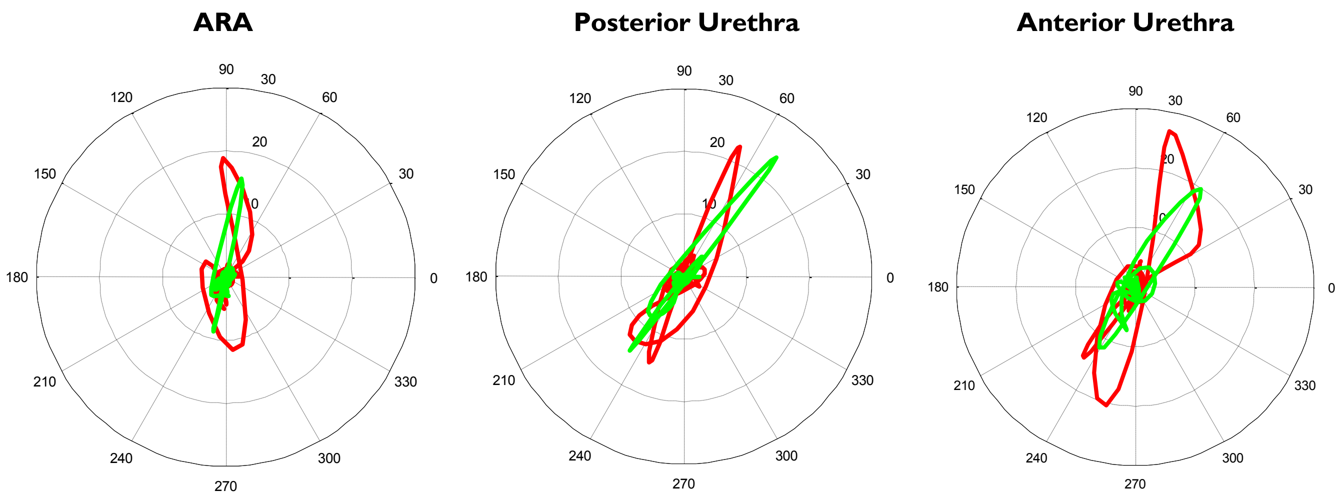


Figure 8.5: Comparison of the mean acceleration of the ARA, and both edges of the urethra during a cough in supine continent (ARA n = 23; urethra n = 11; green line) and SUI (ARA n = 9; urethra n = 5; red line) women. The shaded area represents the Standard Error (SE)..

Table 10.3: Mean and SD of the maximum acceleration of the ARA and urethra in supine during the Knack in supine (Mean ± SD, Unit: cm s^{-2}). (ARA; Continent n = 23 and SUI n = 9: Urethra; Continent n = 11 and SUI n = 5).

	Ventral	**Dorsal**	**Cranial**	**Caudal**
ARA				
Continent	16 ± 6.5	-16 ± 6.4	22 ± 6.6	-18 ± 5
SUI	20 ± 9.2	-18 ± 6.2	30 ± 8.4	-25 ± 5.4
P Value	NS (P = 0.10)	NS (P = 0.26)	**P = 0.003**	**P = 0.0003**
Posterior Urethra				
Continent	21 ± 8	-18 ± 6.3	27 ± 9.9	-19 ± 5.8
SUI	21 ± 3.8	-19 ± 3.3	34 ± 4.7	-28 ± 6.1
P Value	NS (P = 0.43)	NS (P = 0.35)	NS (P = 0.065)	**P = 0.006**
Anterior Urethra				
Continent	21 ± 8.7	-17 ± 5.7	28 ± 7	-23 ± 5.5
SUI	23 ± 6.6	-21 ± 6.0	40 ± 13	-32 ± 9.9
P Value	NS (P = 0.40)	NS (P = 0.10)	**P = 0.02**	**P = 0.02**

8.5.4 Standing displacement:

Even though the sample sizes in standing are small, the differences of the behaviour of the ARA and urethra between groups were highly significant (Table 8.4 and Figures 8.6, 8.7). The polar plots (Figure 8.6) emphasise the significantly greater initial cranio-ventral displacement of the ARA and urethra in the continent group during the PFM component of the Knack [Figure 8.6 green arrows (a)]. During the cough part of the Knack [Figure 8.7 green arrows (b) and Figure 8.7 at t=3 seconds], the ARA of the continent group maintained almost all of the ventral displacement and much of the cranial displacement created by the voluntary PFM contraction. In contrast the ARA of the SUI group appeared to lose almost all the cranio-ventral displacement [Figure 8.7 red arrows (b) and Figure 8.7 at t=3 seconds].

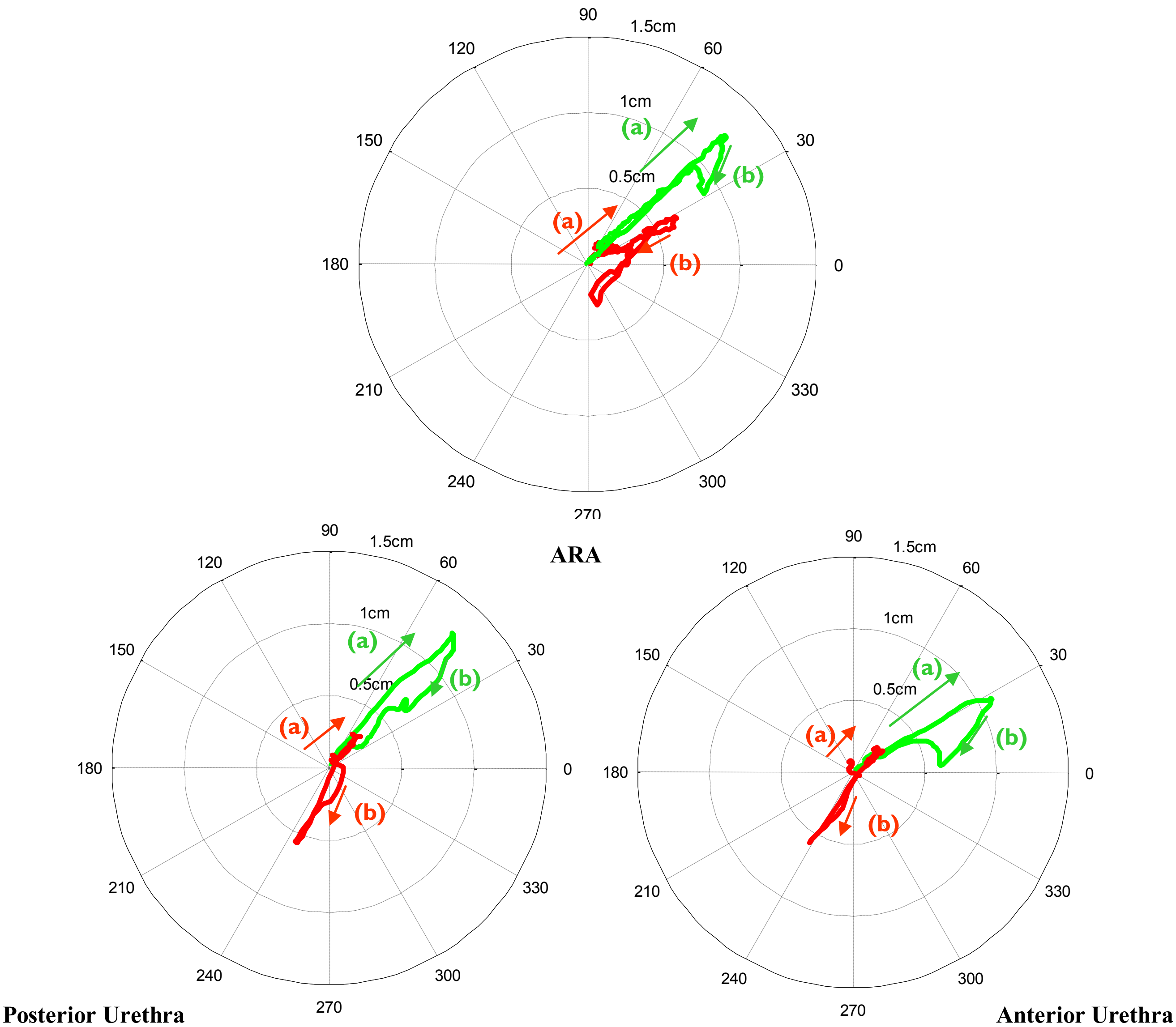


Figure 8.6: Comparison of the mean displacements of the ARA, and both edges of the urethra during the Knack in standing continent (n = 16; green line) and SUI (n = 5; red line) women. Arrow (a) represents the initial PFM component of the Knack; (b) the cough component.

The differences in direction of urethral displacement during the cough part of the Knack also highlights the ability of PFM of the continent group to support the urethra and maintain most of the initial ventral displacement produced by the active PFM component [Figure 8.7 green arrows (b) and Figure 8.7 at t=3 seconds]. In addition, even at the time of maximum caudal displacement (t =3 seconds) the urethra of the continent group maintains a position more cranial than the initial starting position.

There appears to be comparatively little cranio-ventral displacement of the urethra in the SUI group in standing during the active PFM component of the Knack, and this is emphasised in the significant differences between groups (Table 8.4).

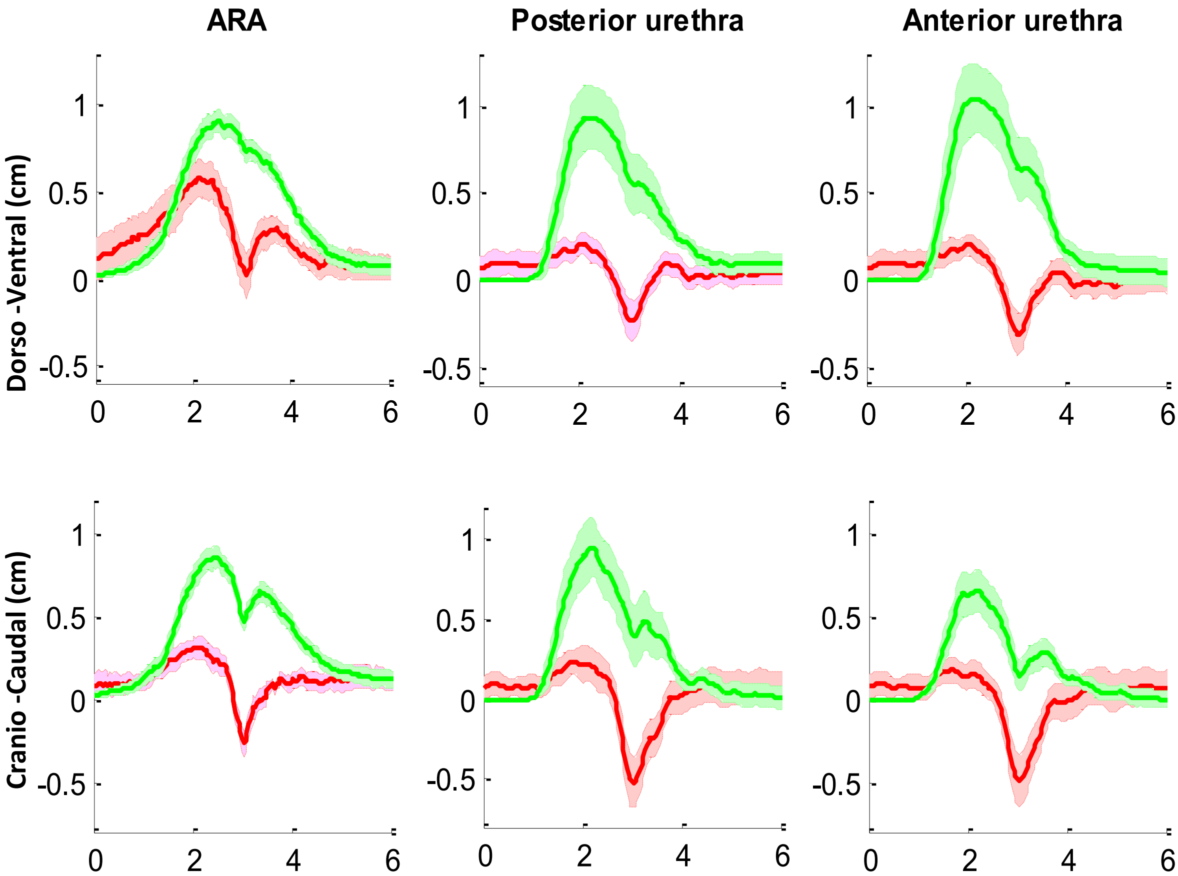


Figure 8.7: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra during the Knack in standing continent (ARA n = 16; urethra n = 5; green line) and SUI (ARA n = 5; urethra n = 5; red line) women. The shaded area represents the Standard Error (SE).

Table 8.4: Mean and SD of the displacements of ARA and urethra at the synchronisation point (t = 3 seconds at maximum caudal displacement) during the Knack in standing (mean ± SD, Unit: cm). (ARA; Continent n = 16 and SUI n = 5: Urethra; Continent n = 5 and SUI n = 5).

	Dorso-ventral	**Cranial-Caudal**	**Angle**
ARA			
Continent	0.68 ± 0.34	0.43 ± 0.38	30 ± 26
SUI	0.06 ± 0.41	-0.22 ± 0.28	310 ± 77
P Value	**P = 0.0009**	**P = 0.0007**	**P = 0.049**
Posterior			
Continent	0.48 ± 0.47	0.35 ± 0.42	20 ± 29
SUI	-0.19 ± 0.48	-0.41 ± 0.54	230 ± 32
P Value	**P = 0.016**	**P = 0.019**	**P < 0.0001**
Anterior			
Continent	0.60 ± 0.50	0.14 ± 0.22	30 ± 46
SUI	-0.25 ± 0.34	-0.39 ± 0.51	220 ± 46
P Value	**P = 0.007**	**P = 0.033**	**P < 0.0001**

8.5.5 Standing Velocity:

In the ventral and cranial directions, the continent group had the maximum velocity before the synchronisation point (before t = 2 seconds), whereas the SUI had the maximum velocity after the rebound (Figure 8.8). Consequentially the maximum values of the velocities of the ARA and urethra were not statistically different due to the differences in timing of displacement. The maximum dorsal caudal velocities of the ARA and urethra were more similar both in timing and magnitude.

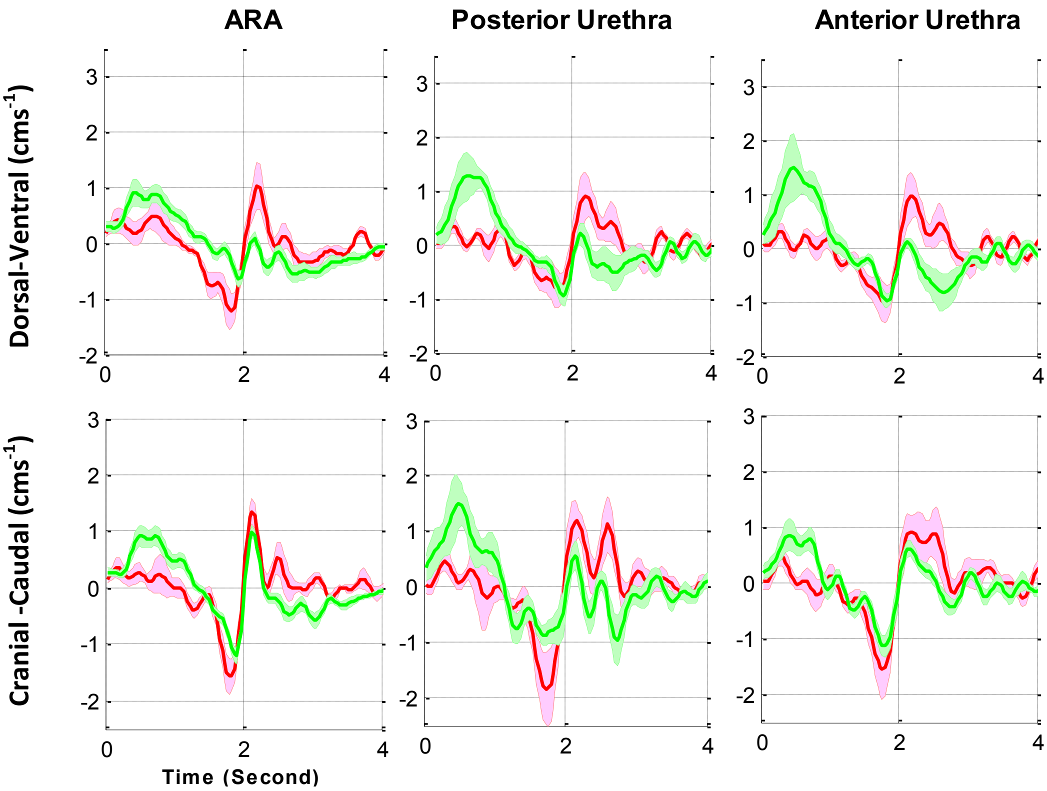


Figure 8.8: Comparison of the average velocities of the ARA, and both edges of the urethra during the Knack in standing continent (ARA n = 16; urethra n = 5; green line) and SUI (ARA n = 5; urethra n = 5; red line) women. The shaded area represents the Standard Error (SE).

8.5.6 Standing acceleration:

The maximum accelerations of the ARA and urethra were slightly greater in the SUI group in all directions (Figure 8.9), but only reached statistical significance in the comparison between the anterior edges of the urethra in the cranial (14 ± 5.0 cm s^{-2}: 25 ± 5.4 cm s^{-2}: (P = 0.005)) and caudal (-13 ± 4.9 cm s^{-2}: -23 ± 7.4 cm s^{-2}: (P = 0.02)) directions. Predictably the maximum accelerations occur at the maximum caudal displacement of the PF structures (t = 2 seconds) and there was a tendency for the tissue of the SUI group to rebound with greater acceleration than the continent group after this point.

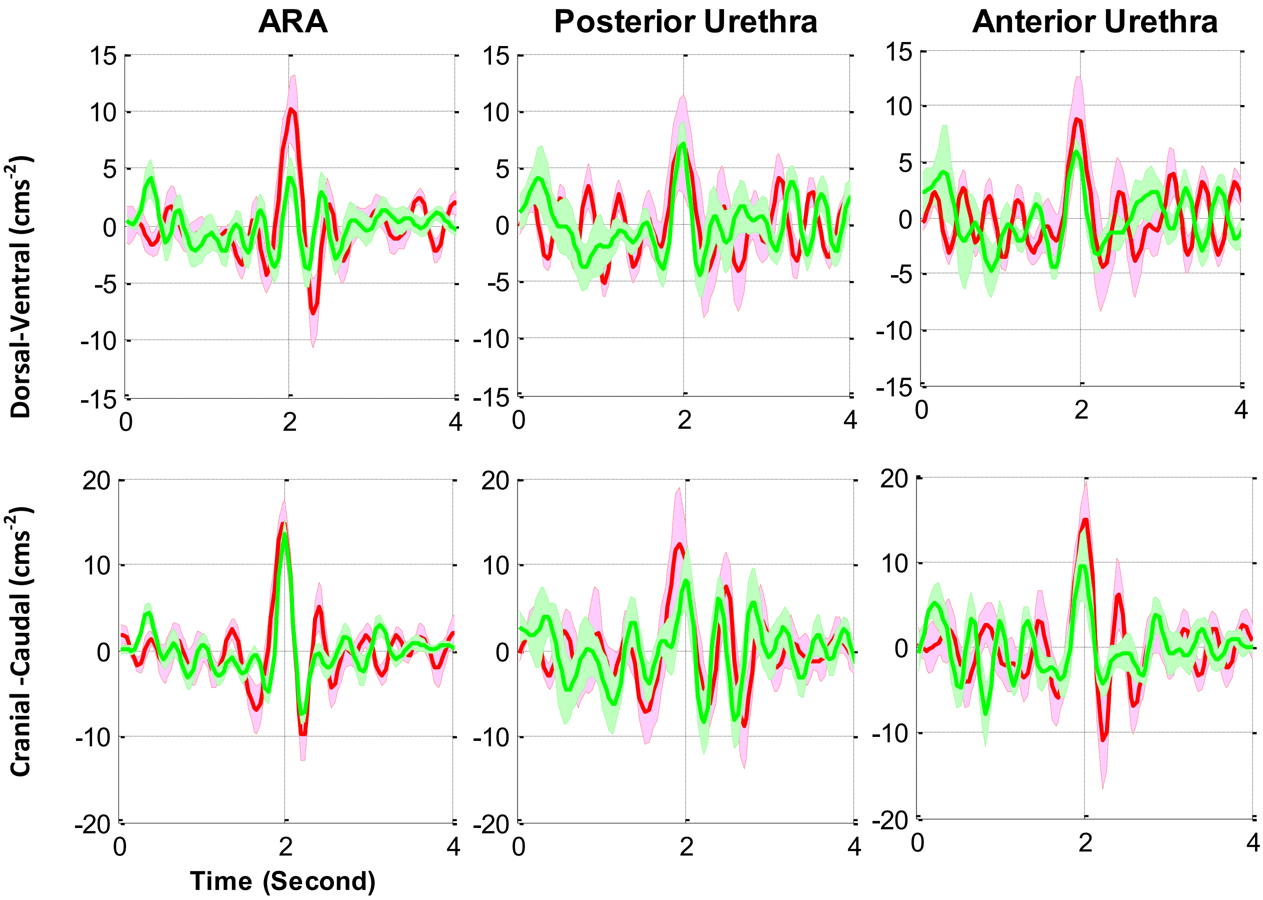


Figure 8.9: Comparison of the acceleration of the ARA, and both edges of the urethra during the Knack in standing (ARA n = 16; urethra n = 5; green line) and SUI (ARA n = 5; urethra n = 5; red line) women. The shaded area represents the Standard Error (SE).

The second section of the results will now compare the Knack and a cough, firstly within groups to indicate whether the IPM are able to distinguish between manoeuvres. Secondly comparisons are made between a cough of continent women, and the Knack of women with SUI, in supine and standing to give an indication of the immediate therapeutic benefit of the Knack in women with SUI.

8.5.7 Within group comparisons of the Knack and cough:

The wave forms produced from a cough alone and a cough with a prior PFM contraction, the Knack, demonstrates equivocally in both groups, that it is very possible to differentiate between the two manoeuvres, predominately by reference to the initial significant cranio-ventral displacement of the ARA and urethra in the Knack, which is absent during a cough (Figures 8.10 continent women, Figure 8.11 SUI women).

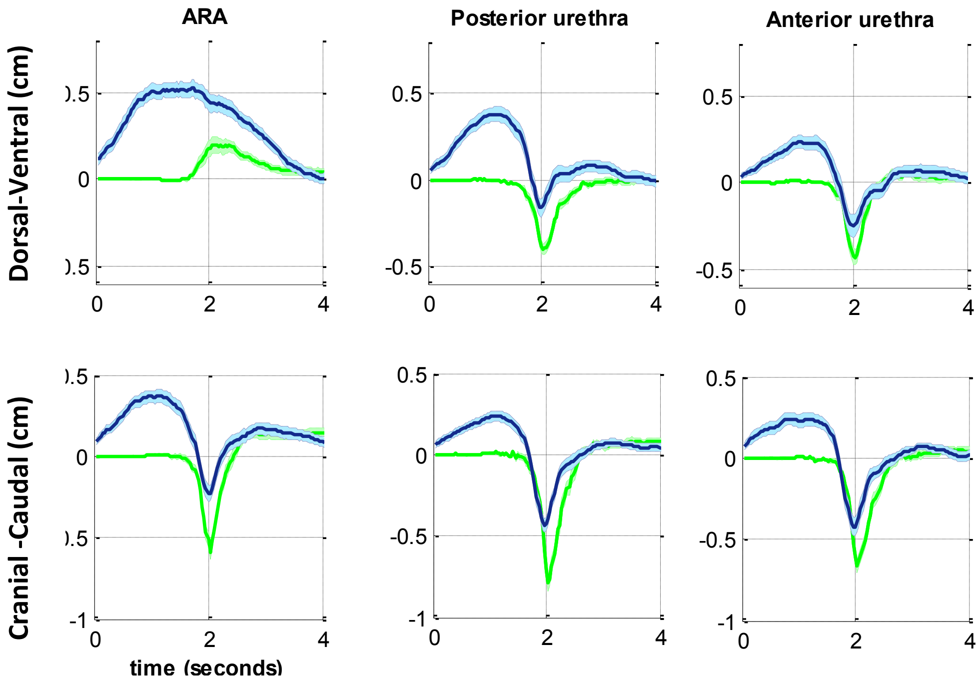


Figure 8.10: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra during a cough in continent women (ARA n = 23; urethra n =23; green line) and the Knack (ARA n = 23; urethra n =11; blue line).

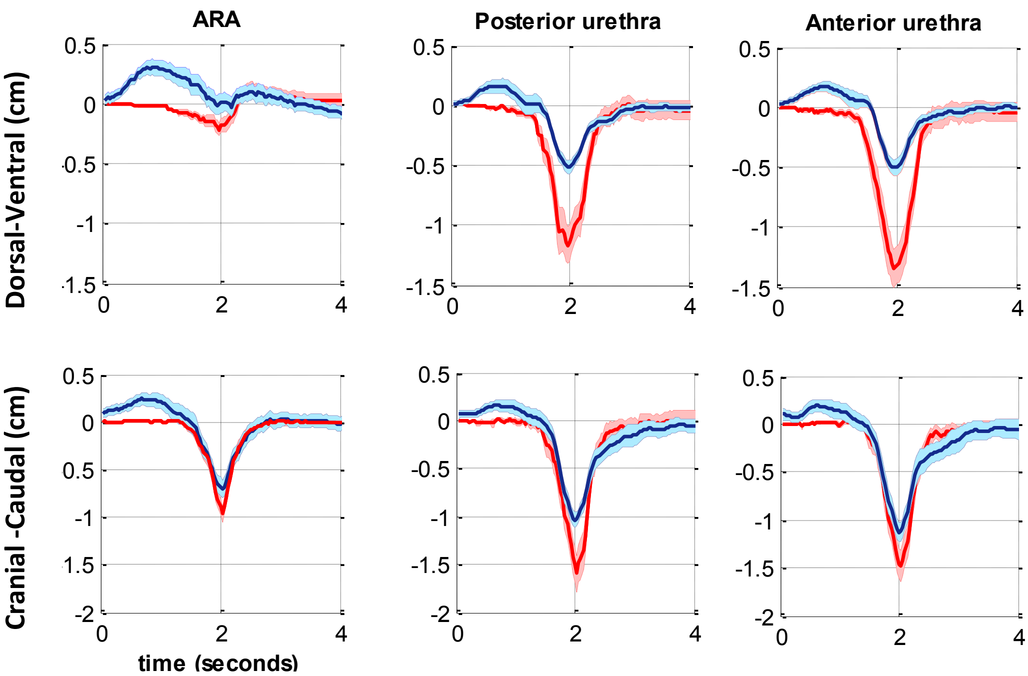


Figure 8.11: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra during a cough in SUI women (ARA n = 9; urethra n = 9; red line) and the Knack (ARA n = 9; urethra n = 5; blue line).

As expected, in both groups, there was significantly less dorso-caudal displacement of the urethra during the Knack than there was during a cough (Table 8.5 and 8.6). In the continent group, there were also significant differences in the amount and direction of ARA displacement, whereas these differences were not significant in the SUI group, although there are strong tendencies in angle and amount of caudal displacement.

Table 8.5: Mean and SD of the displacements of ARA and urethra at the synchronisation point (maximum caudal displacement) during the cough and Knack in supine in continent women.(mean ± SD, Unit: cm; Angle: degrees).(UV = Welch's correction applied for unequal variances)(ARA; Cough and Knack n=23:Urethra;Cough n=23 and Knack n=11).

	Dorso-ventral	**Caudal**	**Resultant**	**Angle**
ARA				
Cough	0.18 ± 0.36	-0.63 ± 0.37	0.77 ± 0.36	285 ± 40
Knack	0.43 ± 0.32	-0.24 ± 0.25	0.67 ± 0.25	330 ± 36
P Value	**P = 0.01**	**P < 0.0001**	**NS** P = 0.16	**P = 0.0003**
Posterior				
Cough	-0.41 ± 0.21	-0.80 ± 0.27	-0.92 ± 0.28	240 ± 12
Knack	-0.16 ± 0.24	-0.40 ± 0.17	-0.51 ± 0.19	260 ± 34
P Value	**P = 0.003**	**P < 0.0001**	**P < 0.0001**	**NS** P= 0.10 (UV)
Anterior				
Cough	-0.43 ± 0.28	-0.66 ± 0.25	-0.84 ± 0.30	240 ± 16
Knack	-0.26 ± 0.34	-0.41 ± 0.28	-0.59 ± 0.34	250 ± 30
P Value	**NS** P = 0.08	**P = 0.007**	**P = 0.02**	**NS** P= 0.17 (UV)

Table 8.6: Mean and SD of the displacements of ARA and urethra at the synchronisation point (maximum caudal displacement) during the cough and Knack in supine in SUI women (mean ± SD, Unit: cm; Angle: degrees). (UV = Welch's correction applied for unequal variances) (ARA; Cough and Knack n= 9: Urethra; Cough n = 9 and Knack n = 5).

	Dorsal	**Caudal**	**Resultant**	**Angle**
ARA				
Cough	-0.20 ± 0.26	-1.0 ± 0.42	-1.1 ± 0.40	260 ± 20
Knack	-0.02 ± 0.37	-0.69 ± 0.38	-0.82 ± 0.36	280 ± 33
P Value	**NS** P = 0.13	**NS** P = 0.057	**NS** P = 0.087	**NS** P = 0.062
Posterior				
Cough	-1.1 ± 0.42	-1.7 ± 0.61	-2.0 ± 0.71	235 ± 5
Knack	-0.47 ± 0.17	-1.00 ± 0.14	-1.10 ± 0.12	245 ± 11
P Value	**P = 0.006**	**P = 0.006 (UV)**	**P = 0.004 (UV)**	**NS** P = 0.059
Anterior				
Cough	-1.22 ± 0.48	-1.7 ± 0.51	-2.1 ± 0.65	230 ± 10
Knack	-0.41 ± 0.30	-1.10 ± 0.24	-1.20 ± 0.27	250 ± 17
P Value	**P = 0.003**	**P = 0.016**	**P = 0.013**	**P = 0.045**

The next section presents the potential immediate rehabilitative effects of the Knack in women with SUI by comparing a cough of continent women with the Knack of women with SUI, in supine and standing.

8.5.8 Supine comparisons between the Knack manoeuvre in women with SUI and a cough in continent women:

Comparing the displacement produced by a cough alone from continent women to the Knack from a woman with SUI, highlights the immediate change in the behaviour of the ARA and urethra that could occur when a PFM pre-contraction is added to a cough during a rehabilitation programme for SUI (Figure 8.12).

Although there was more initial ventral displacement of the ARA in the SUI group during a Knack in comparison with only a cough from the continent group; the ARA of the SUI group lost almost all this ventral displacement during the cough component of the Knack, whereas the continent women sustained the ventral displacement until the end of the manoeuvre.

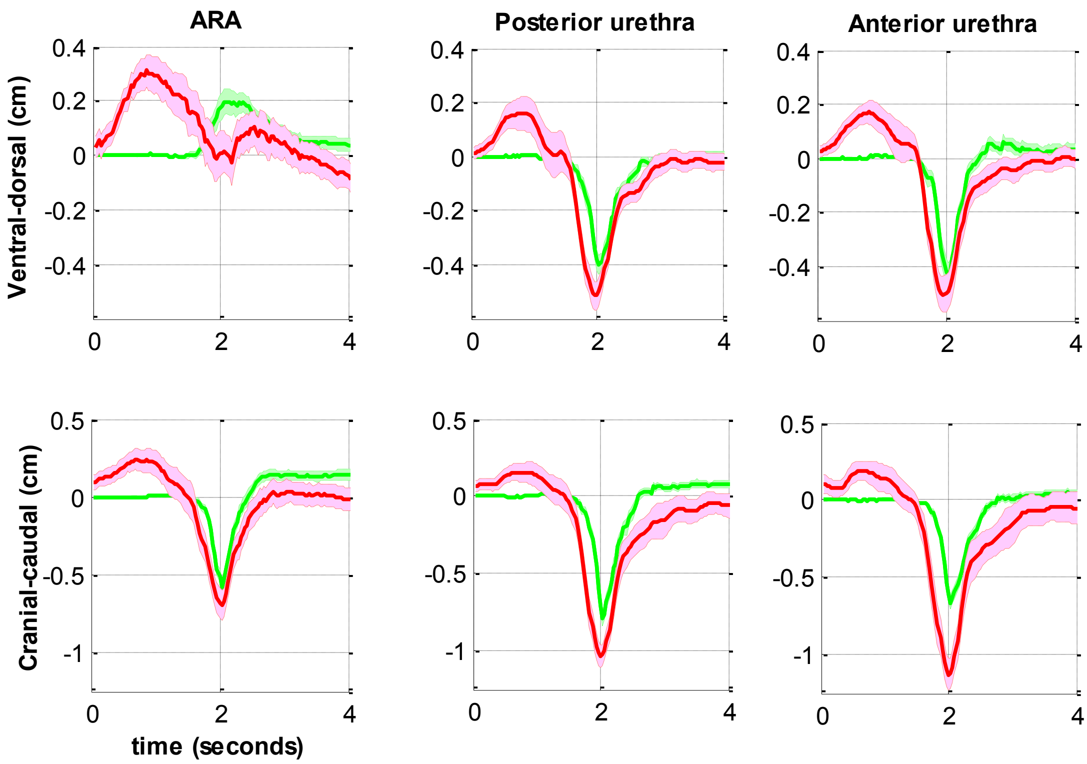


Figure 8.12: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra in supine during a cough in continent (ARA n = 23; urethra n = 23; green line) and the Knack in SUI (ARA n = 9; urethra n = 9; red line) women. The shaded area represents the Standard Error (SE).

Statistically, at the centre of the cough, there were no significant differences between groups in displacement of the ARA in any direction. The dorsal displacements of the urethra between groups were very similar and the overall cranial displacement of the ARA and posterior edge show little difference between the two manoeuvres. In the caudal direction (Y) and overall displacement (R) of the anterior edge of the urethra there was significantly greater displacement in the SUI compared to continent groups (P=0.004 and P=0.08 respectively), although the velocities and accelerations were very similar.

8.5.9 Standing comparisons between the Knack manoeuvre in women with SUI and a cough in continent women:

Comparing the displacement in standing produced by a cough from continent women to the Knack from a woman with SUI indicated that the displacement of ARA and both edges of the urethra were very similar except for the initial cranio-ventral displacement that occurred at the voluntary PFM contraction component of the Knack (Figure 8.13). Unlike in supine, even the caudal displacement of the anterior edge of the urethra showed no significant differences.

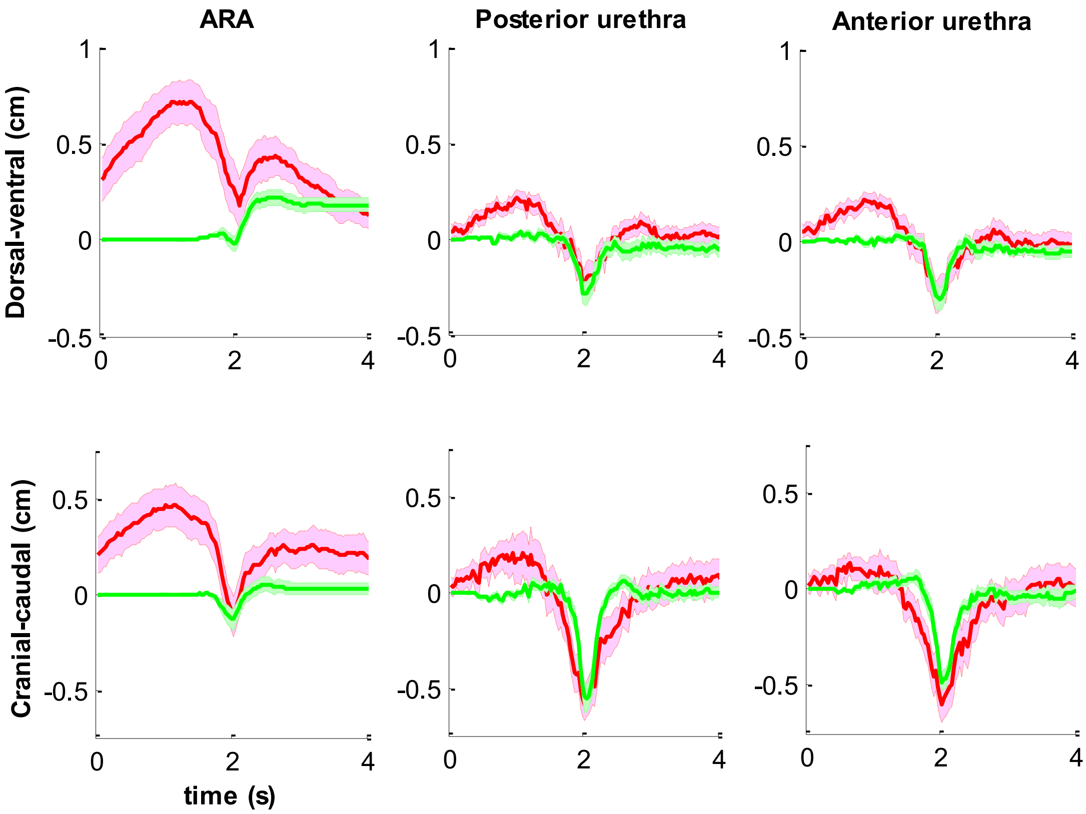


Figure 8.13: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra in standing during a cough in continent (ARA n = 16; urethra n = 16; green line) and the Knack in SUI (ARA n = 5; urethra n = 5; red line) women. The shaded area represents the Standard Error (SE).

8.6 Discussion

TP ultrasound combined with IPM is specific enough to be able to distinguish between a Knack and the cough and informs us whether or not there is a coordinated, effective PFM contraction, sufficiently able to support the urethra during a cough.

Significant differences occur between the behaviour of both the urethra and ARA of continent and SUI women during the Knack in supine and standing. This is the first study to describe the trajectory of the ARA and urethra during the Knack in continent and SUI women. In both groups, the Knack has three basic stages:

1. During the active PFM contraction there is an initial cranio-ventral displacement of both the ARA and urethra;
2. During the cough component, there is a dorso-caudal displacement of the urethra and the ARA of SUI women and a predominately caudal displacement of the ARA in continent women;
3. On return to the resting position. The urethra of both groups returns to the original starting position, however the ARA of SUI women tends to rest in a position slightly further dorso-caudal and the ARA of continent women slightly more dorso-cranial than their original start position.

Although there is no physiological reason why women without PF dysfunction would need to perform the Knack, comparing the manoeuvre between groups does help to understand how the PF of continent women differs to that of women with SUI. The displacement of the ARA through the PFM contraction component of the Knack illustrates the significantly greater ventral displacement of the continent group compared to the SUI women, and their ability to maintain this ventral shift through the cough component. This, along with a reduced caudal displacement, once again illustrates how the PFM of continent women are better able to resist the force created by the cough, which implies greater stiffness of the PF.

The PFM contraction also results in a significantly greater ventral displacement of the posterior edge of the urethra in the continent compared to the SUI group and there is significantly less displacement of this edge throughout the cough component of the Knack. Interestingly in the continent group, during the cough component, there is less overall displacement of the posterior edge compared to the anterior edge, especially in the dorsal direction. In continent women, there are also no differences in the amount of caudal displacement in the urethral edges. Given the comparatively reduced fascial attachments of the posterior edge with respect to the anterior edge (Mostwin, 1991), the findings of this current study supports our hypothesis that the PFM in the continent group provide greater support to the urethra than the SUI group. In addition, in the SUI group, there is slightly greater displacement of the posterior edge than the anterior edge in the dorsal direction. The active PFM contraction held during the cough reduces the cranio-ventral displacement of the anterior edge of the urethra in both groups and there is significantly less overall displacement in the continent group, particularly in the caudal direction. Interestingly though, when comparing the dorsal displacement of the urethra during a cough with the displacement when a PFM contraction has been added before the cough(the knack) (Table 8.5) the dorsal displacement of the posterior edge is significantly reduced, but the anterior edge is not. It therefore appears that in the continent group, the anterior edge is less affected by the active PFM contraction held during a cough than the posterior edge.

In the SUI group, although the addition of a PFM contraction during a cough is less effective than that of the continent group, it significantly reduces the amount of dorso-caudal displacement of both edges of the urethra in comparison to a cough without a PFM pre-contraction. Unlike the continent group, it also significantly alters the angle and reduces the dorsal displacement of the anterior edge. The Knack reduces the displacement, velocity and acceleration of the urethra, so much so that the kinematic properties are very comparable to that of a cough in continent women, particularly in standing. In standing, although the initial cranio-ventral displacement of the ARA in the SUI group was lost during the cough component of the Knack; unlike in supine, there still remained greater ventral displacement of the ARA during the cough part of the Knack in SUI women than that of the cough in continent women. Clinically this would suggest the ability of the SUI to maintain sufficient ventral compression and support of the pelvic structures towards the SP.

During the Knack in SUI women, particularly in supine, even with the addition of a PFM contraction, the anterior edge of the urethra is still displaced significantly more caudally than that of a continent woman coughing. This may provide one other alternative explanation of why some women with SUI fail to significantly reduce the volume of urine leakage with the addition of the knack manoeuvre in the study by Miller et al (Miller *et al.*, 2008). Our results indicate that in a caudal direction, even with the addition of the knack, the urethra of women with SUI is still displaced more than that of continent women. The knack can be a compensatory mechanism for some women with SUI (Miller JM *et al.*, 1997;Miller *et al.*, 1998;Miller *et al.*, 2008), so in the future during rehabilitation, if the knack manoeuvre did not reduce the volume of urine leaked; using ultrasound and IPM, there may be the potential to clarify why. For example, a woman with SUI could have both adequate urethral sphincteric competence, appropriate timing of the PFM, but was unable to significantly reduce caudal or dorsal urethral displacement with the knack manoeuvre. If after adequate training, the PFM were still unable to compensate for this urethral hypermobility, the use of IPM combined with TP ultrasound may provide us with the indication of why conservative care was not helping and help indicate whether surgical intervention was necessary.

Similar to the only other study quantifying and comparing urethral displacement during a cough and the Knack, our groups indicated a significant reduction in the amount of dorso-caudal displacement in both groups (Miller *et al.*, 2001). The displacement values measured by Miller et al during both manoeuvres were very much smaller than this current study. Normal sampling variations could account for the differences, and specifically parity status will have affected the displacement values in their control group, as they were nulliparous; however their study group were of comparable parity and were also older. Methodological differences and reliability could account for the disparity in values, as the same group has more latterly questioned the reproducibility of the methodology used in the 2001 study (Armstrong *et al.*, 2006).

8.7 Conclusions

This current study has indicated that TP ultrasound combined with IPM is specific enough to be able to distinguish between the Knack and a cough without pre-contraction of the PFM. IPM allows visualisation of the displacement of the ARA, and therefore can determine the pattern of PFM activation. In the future, IPM could be used to determine whether the automatic timing function of the PFM is ever restored.

The PF of SUI women is more compliant than that of continent women, yet the addition of an active PFM contraction prior to and during a cough, is sufficient to reduce the displacement, velocity and acceleration of the urethra, to comparable values of a continent women coughing. IPM therefore can inform us whether a woman is able to use their PFM effectively to displace and support the urethra during a cough.

During the Knack, there are significant differences between the behaviour of both the urethra and ARA of continent and SUI women. There is less dorso-caudal displacement, velocity and acceleration of the ARA and urethra in continent women than in women with SUI consequent to the Knack which highlights the greater stiffness and control of the PFM and urethra in continent women.

This study has highlighted the immediate potential benefits of the Knack as a rehabilitation tool and it illustrates the possibility of IPM to quantify the effect of a treatment intervention. As such, in the future, IPM may be able to confirm the effectiveness of the PFM in conservative rehabilitation of SUI, and other PF dysfunctions such as prolapse, or indeed whether conservative intervention is at all indicated.

TP ultrasound combined with these novel IPM methods has indicated the immediate benefits of a PFM contraction held prior to and during a cough. The next chapter describes a new vaginal palpation assessment scale of PFM function which it is hoped can determine, without the availability of ultrasound, the ability of the PFM to provide external support of the urethra during a cough.

9 A Vaginal Palpation Assessment Scale of Pelvic Floor Muscle Function: Inter-Observer Reliability

9.1 Introduction

Digital palpation of the pelvic floor muscle (PFM) is an easy to perform, inexpensive physical examination and is routinely used to assess the PFM and surrounding areas at rest, during contraction and relaxation. The reliability of clinical scores of strength, endurance, and movement of the pelvic floor (PF) has been evaluated and a number of scales have been developed (Chapter 2, Section 2.8). The most widely used scales are the PERFECT scheme (modified Oxford scale) (Laycock & Jerwood, 2001) and Brink score, (Brink *et al.*, 1994;Laycock & Jerwood, 2001) which both emphasise strength and endurance of PFM contraction. However even if the muscle is reported to be strong, is its contraction useful? The answer may depend on the functional requirement of the PFM at that particular time.

As described earlier, it is thought that the PFM perform multiple functions: continence and pelvic organ support (DeLancey, 1990;Howard *et al.*, 2000); sexual function (Baytur *et al.*, 2005); respiration (Hodges *et al.*, 2007) spinal stability and containment of intra-abdominal pressure (IAP) (Hemborg *et al.*, 1985;Pool-Goudzwaard *et al.*, 2004;Smith *et al.*, 2008). The ability of the PFM to generate strength may not be as important for continence function as was previously considered as many women with a strong PFM (Morin et al., 2004; Theofrastous et al., 2002), or greater PFM activity (Smith et al., 2007) have SUI, and conversely a number of continent women have a weak pelvic floor (Miller et al., 1998). Indeed the latest Cochrane review of PFM training versus no treatment, or inactive control treatments for urinary incontinence in women, concluded that after a PFM rehabilitation programme, although continence status improves, the strength of the PFM does not significantly improve and that other aspects of muscle function that were not measured, for example timing of contraction during a cough or sneeze, might contribute to the perception of improvement in incontinence (Dumoulin & Hay-Smith, 2008).

As was shown in the previous chapters, it does seem important that the PFM have a well timed contraction that is able to adequately support the urethra during activities that increase IAP. Chapter 6 indicated that women with stress urinary incontinence (SUI) have greater displacement of the urethra during a cough than asymptomatic women, yet Chapter 8 indicated that if they performed a voluntary PFM contraction prior to and during a cough (The Knack), the displacement of the urethra and ano-rectal angle (ARA) was reduced to within similar ranges to asymptomatic women performing a cough alone.

During a PFM contraction, a sling of fibrous connective tissue underneath the urethra, is pulled anteriorly toward the symphysis pubis (SP), thereby compressing the urethra (Delancey, 1988). However it is reported that even when a voluntary PFM contraction is performed correctly, not all women are able to displace the urethra sufficiently to increase the intra-urethral pressure (Bump *et al.*, 1991). Conversely selective women without visible puboccocygeus muscle on MRI are still able to increase urethral pressure (Miller *et al.*, 2004).

In the author's opinion, the inability of a PFM contraction to produce stabilization of the urethra during a rise of IAP is likely due to a number of factors including inhibition or over activity of components of the PFM, damage to the neural, fascial or muscular tissue of the PF, interaction of the other muscles of the abdominal-pelvic cylinder, and the overall relative resting position of the vagina, bladder and urethra. It would seem useful to have a simple digital measurement of the PFM that evaluated function so it could be determined whether or not the PFM could do what they needed to do, irrespective of position of the pelvic organs, co-ordination of other muscle groups or pathology present. So for rehabilitation of women with SUI, are we able to measure whether a voluntary PFM contraction has the ability to stabilise the urethra during a cough?

The investigation of reliability is a prerequisite in the development of any new scale. As digital palpation is essentially a subjective measurement; the accuracy of manual muscle testing is dependent upon the experience, training and therefore interpretation of the results by the examiner. Inter-observer variability has to be established where there is more than one assessor as differences between observers are a potential threat to the validity of a study and cannot be controlled for in any study design. It has been shown that with sufficient training and discussion, as indicated with two digital vaginal palpation studies; (Jeyaseelan *et al.*, 2001;Devreese *et al.*, 2004) considerable agreement can be attained, however to date, there remains considerable debate as to whether vaginal palpation of PFM strength has sufficient sensitivity and reproducibility for scientific purposes (Messelink *et al.*, 2005;Bo & Finckenhagen, 2001). Current digital scales of the PFM do not assess whether the PFM are able to support the urethra during raises in IAP, they measure strength, endurance and location of displacement of the PFM (Brink *et al.*, 1994;Laycock & Jerwood, 2001). This chapter describes the initial developments, the feasibility and reliability of a functional scale of PFM measurement that seem to be relevant to women with SUI. The Functional Scale is a proposed indicator to measure whether a voluntary PFM contraction can displace the PF sufficiently to support the urethra, irrespective of strength or anatomical variations between subjects, maintaining the external urethral support during a cough. Two validated pelvic floor palpation scales: the PERFECT scheme or modified Oxford Scale (Laycock & Jerwood, 2001) and the Deep and Superficial PFM displacement scales (Devreese *et al.*, 2004) were used for comparison. Subsequent chapters will explore the validity of the measurement scales.

9.2 Aims:

9.2.1 To investigate the inter-observer reliability of a novel scale of PFM function, the Functional Palpation Scale, developed by the author (RLJ), which assesses the ability of a voluntary PFM contraction to displace the urethra and maintain support of the urethra during a cough.

9.2.2 To investigate the inter-observer reliability of two validated pelvic floor palpation scales: the PERFECT scheme or modified Oxford Scale (Laycock & Jerwood, 2001) and the Deep and Superficial PFM displacement scales (Devreese *et al.*, 2004).

9.3 Methods:

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3, however in addition to the thirty two (32) women available for ultrasound analysis; a further four (4) women were available for digital evaluation. From the total of thirty six (36) female volunteers in the study to evaluate the digital palpation scales and evaluate differences between continent and SUI women, a convenience sample of twenty four (24) women was used to assess inter-observer reliability.

9.3.1 Inter-observer Reliability of Physical Examination:

Twenty-four volunteers were evaluated by two experienced examiners whilst being blinded to each other's findings and the continence status of the volunteers. The first examiner (RLJ) was an experienced physiotherapist with greater than 12 years of practice and education in PFM assessment and rehabilitation; the second examiner (CP) was a uro-gynaecologist with over 15 years experience as a specialist in Female Urology and Incontinence and Pelvic Reconstructive Surgery. At least 30 minutes time lapse occurred between the test sessions of both examiners.

The female volunteers were in a crook lying position and a pillow placed under their head. Thorough instructions to the volunteer to elicit a PFM contraction followed International Continence Society (ICS) guidelines “squeeze the muscles of the pelvic floor as if attempting to stop the flow of urine or prevent wind or flatulus escaping” with the addition of “squeeze around the back passage, as if you were trying to prevent breaking wind (flatus); bring that feeling forward towards the urethra/pubic bone and then lift, as if you were elevating the PFM, whilst breathing normally”.

The subjects were asked to maintain their maximum perceived contraction for five seconds with a five second rest in-between contractions. For all items, the best performance of two or three contractions was used for analysis. The sequence of the tests and assessors was randomised and a five minute rest period was given to the patient between each test.

Three digital positions and measurement scales were evaluated:

1. Functional Palpation Scale, developed by the author (RLJ),
2. Modified Oxford Scale (Laycock, 1992),
3. Deep and superficial scale of the PF (Devreese *et al.*, 2004).

The following section describes these three scales in detail.

9.3.1.1 Functional Palpation Scale: The lubricated index finger of a gloved hand was inserted initially palmar side orientated towards the caudal part of the vagina, and then the hand was rotated 180 degrees. The pad of the index finger was then extended cranially to locate the urethro-vesical junction (UVJ) (Figure 9.1). The volunteer was asked to perform a voluntary PFM contraction as described above, then whilst holding the contraction, to cough as hard as they could. The functional measurement of voluntary PFM contraction was recorded according to the criteria described in Table 9.1.

Table 9.1: Functional Scale of PFM contraction

Grade	Description
0	Absent: not present
1	Poor: present to a minor degree able to feel sensation on one aspect of palpating finger
2	Fair: able to feel sensation on two aspects of palpating finger
3	Good: obvious sensation of displacement on all aspects of palpating finger
4	Functional: able to maintain displacement on cough

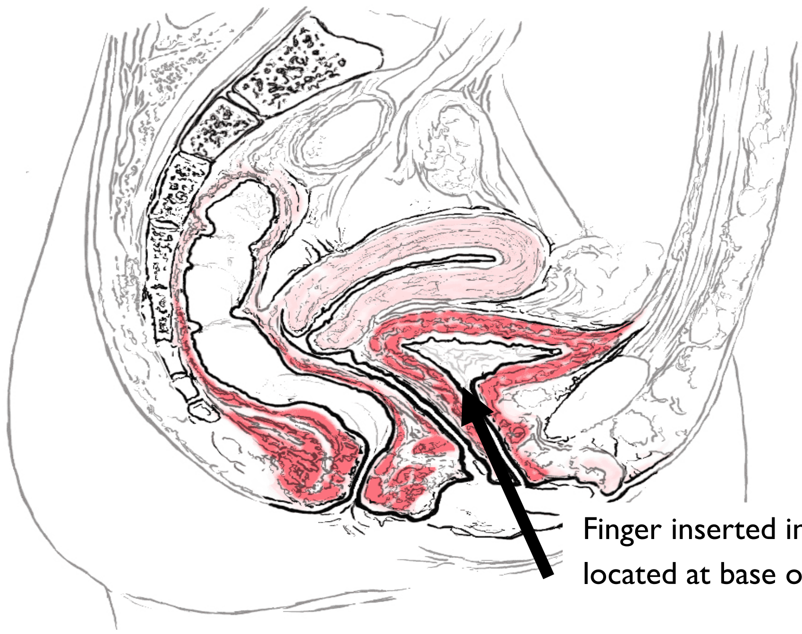


Figure 9.1: Sagittal cross section of female pelvis with arrow indicating position of examiner's finger at the UVJ. Picture courtesy of Maeve Whelan, Specialist Women's Health Physiotherapist, Dublin, Ireland

9.3.1.2 Modified Oxford Scale (Laycock, 1992)

The PFM can be described and examined on the vertical and horizontal planes or clock faces in order to clarify location of the palpating finger (Whelan, 2008). On the vertical clock face, which is the plane of reference described by Laycock, (Laycock, 1992) the symphysis pubis (SP) is at 12 o'clock and perineal body at 6 o'clock (Figure 9.2). On the horizontal plane, the coccyx is at 12 o'clock and perineal body at 6 o'clock (Figure 9.2). The lubricated index finger of a gloved hand was inserted with the palmar side oriented towards the caudal part of the vagina, approximately 4 cm to 6 cm inside the vagina and positioned at 4 o'clock (patient's left) and 8 o'clock (patient's right) in the vertical plane (Figure 9.2 a, b) to monitor muscle activity of pubococcygeus (correctly known as puboviscerallis).

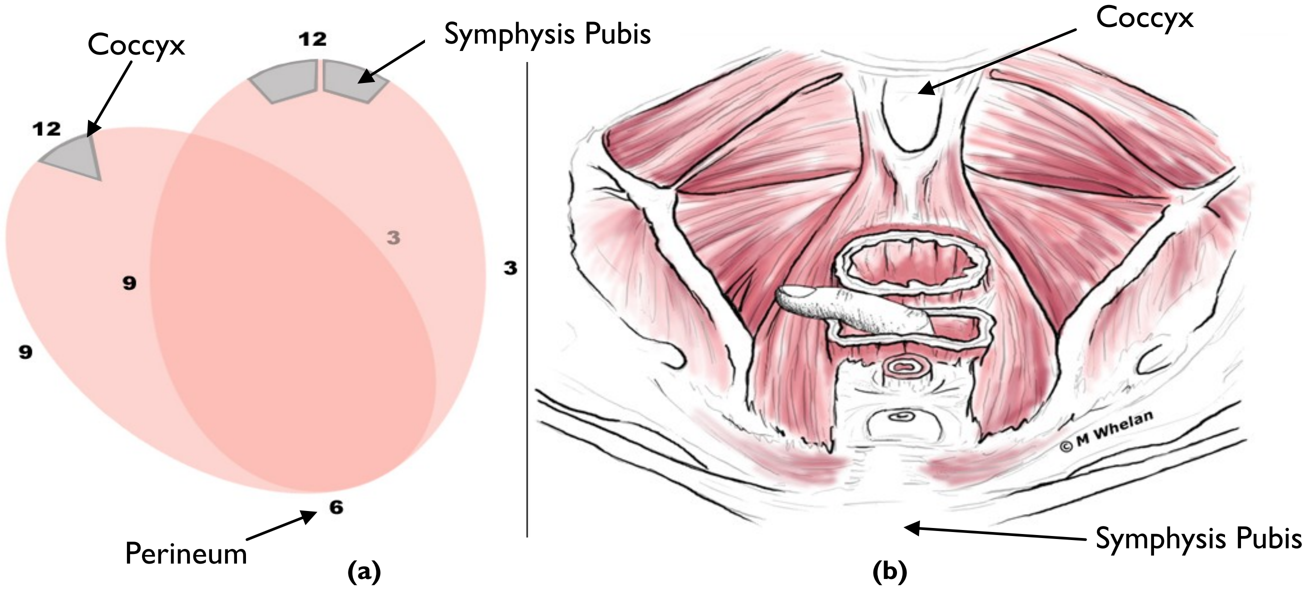


Figure 9.2: (a) Vertical Clock (Symphysis Pubis at 12 o'clock, perineal body at 6 o'clock) and Horizontal Clock (coccyx at 12 o'clock, perineal body at 6 o'clock) demonstrating relative positions of symphysis pubis, perineum and coccyx; **(b):** Approximate finger position to measure 8 o 'clock on vertical clock. Pictures courtesy of Maeve Whelan, Specialist Women's Health Physiotherapist, Dublin, Ireland.

Both the left and right pubococcygeus were graded using the modified Oxford Scale by RLJ (Laycock, 1992) (Table 9.2) (Appendix 2b); however for the purposes of inter-observer reliability (and for validity measurements in Chapter 10), they were also given an overall single score by rounding down. For example, if the left side scored 3 and the right 4, the overall score would be 3. Both examiners rated whether or not there was symmetry of PFM contraction.

Table 9.2: Modified Oxford Scale for digital evaluation of PFM strength(Laycock, 1992)

Grade	Description
0	Nil
1	Flicker
2	Weak
3	Moderate, slight lift of the examiners fingers, no resistance
4	Good, sufficient to elevate the examiners fingers against light resistance
5	Strong, sufficient to elevate the examiners fingers against strong resistance

9.3.1.3 Deep and superficial scale of the PF (Devreese *et al.*, 2004).

The index finger was placed deeper into the vagina, in the horizontal plane, so that the pad of the index finger rested upon the coccyx. The finger was then moved immediately lateral so that the pad of the palpating finger at 10 o'clock and 2 o'clock would palpate the iliococcygeus with the base of the palpating finger in contact with the puboccoccygeus (Figure 9.3).

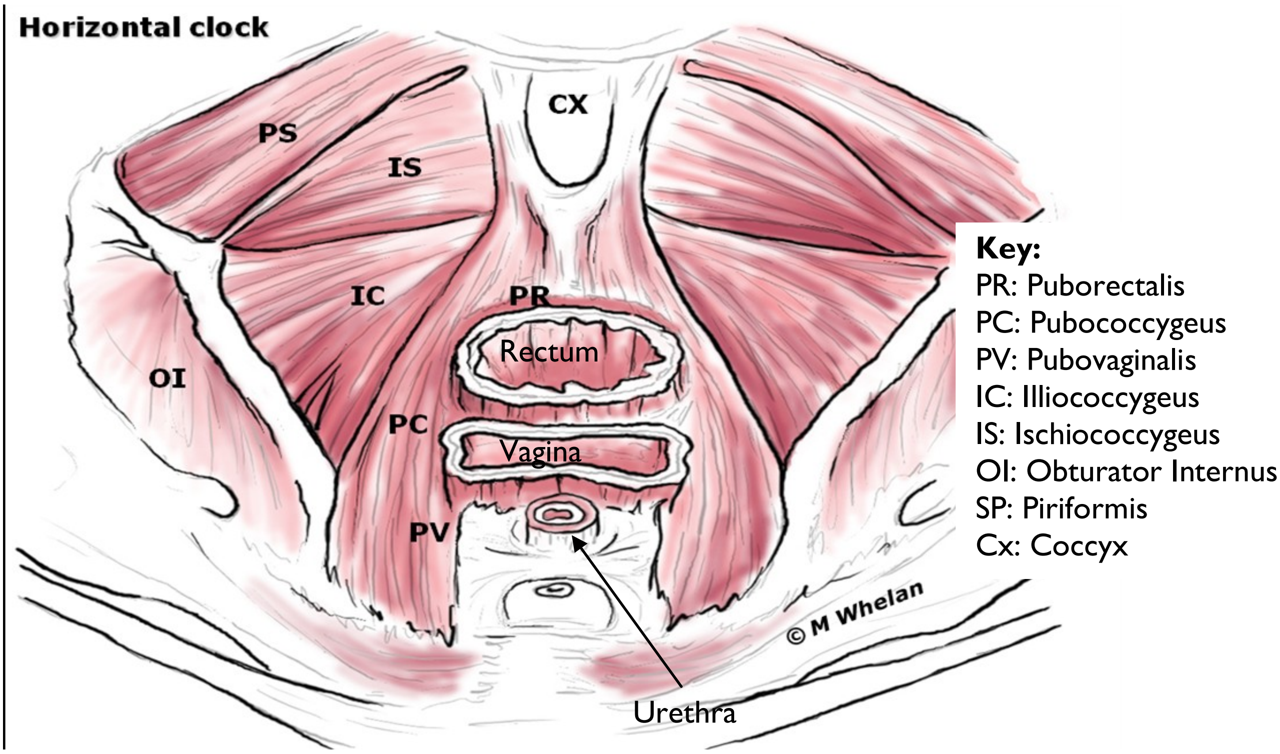


Figure 9.3: Schematic of the Pelvic Floor illustrating the orientation of the horizontal clock, coccyx at 12 o'clock, perineal body at 6 o'clock.Picture courtesy of Maeve Whelan, Specialist Women's Health Physiotherapist, Dublin, Ireland.

Both the left and right sides were graded separately by RLJ, however the superficial (Table 9.3a) and deeper (Table 9.3b) aspects of the PFM were evaluated centrally by both RLJ and CP, according to the criteria described by Devreese et al 2004.

Table 9.3a*:* Superficial scale for digital evaluation of PFM displacement (Devreese *et al.*, 2004)

Grade	**Description**
0	No contraction noticeable
1	Flicker of contraction
2	Inward displacement and obvious squeeze around proximal part of the testing finger
3	Inward displacement and strong squeeze around proximal part of testing finger

Table 9.3b*:* Deep scale for digital evaluation of PFM displacement (Devreese *et al.*, 2004)

Grade	Description
0	No contraction noticeable
1	Flicker of contraction
2	Inward displacement of the distal part of the testing finger without total extension
3	Inward displacement of the distal part of the testing finger with total extension
4	Inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient without contact with the cranial part of the vagina
5	Inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient. The pelvic floor muscle tightens around the finger

Devreese et al had observed in their study that irrespective of training, they were unable to obtain reasonable reliability when distinguishing between left and right sides of the PFM muscle, and only a central measurement was sufficiently accurate (personal communication). However it is important to emphasise that a central measurement is not palpating the muscle and is a result of the muscles at each side producing a lift.

9.3.2 Statistical analysis:

The highest of the maximum voluntary contraction scores was used for digital evaluation of function and strength. Statistical comparisons using one tailed Mann Whitney test for ordinal data were performed to evaluate the level of significant difference between groups. Statistical comparisons using two-tailed Wilcoxon matched pairs was used to evaluate levels of significant differences within groups, for example comparing the left and right side of a PFM contraction in continent women.

The inter-observer reliability was evaluated using a linear weighted Kappa (Kw) for items with more than two categories. As the value of Kappa does not reflect strength of agreement, interpretation of Kappa is based on the criteria set by Landis and Koch (Landis & Koch, 1977) (Table 9.4). Percentage of agreement was calculated for whether or not there was symmetry of contraction.

Table 9.4: Criteria for the interpretation of Cohen's Kappa.

Value of Kappa	Interpretation
<0	Poor
0.00 to 0.20	Slight
0.21 to 0.40	Fair
0.41 to 0.60	Moderate
0.61 to 0.80	Substantial
0.81 to 1.00	Almost perfect

9.4 Results:

Inter-observer agreement of digital examination will be presented before comparing continent and SUI women for significant differences.

9.4.1 Inter-observer Reliability in Physical Examination:

There were no significant differences between age, parity or body mass index (BMI) of the two groups tested for reliability analysis (Table 9.5).

Table 9.5: Mean and SD of Age, Parity, Body Mass Index (BMI), and Continence Severity Scale (CSS)

	Continent (N = 15)	SUI (N = 9)	P Value
Age	39.3 ± 10.5	47.8 ± 13.2	0.12
Parity	0.8 ± 0.97	1.6 ± 0.7	0.07
BMI	22.8 ± 2.8	22.8 ± 4.3	0.17
CSS	Continent	5 Slightly 4 Moderately	

There was substantial level of agreement in all palpation scales (K_w= 0.62 to 0.78). Levels of agreement are reported in Tables 9.6-9.10 and the detailed results of the classification by both examiners of muscle strength, displacement and function are listed in Table 9.11. 95% CI were also very reasonable (0.53 to 0.95), except within the Superficial scale (0.36 to 0.88).

On measuring symmetry of contraction from left to right in the Oxford scale, agreement was reached in all but one instance (96%).

Table 9.6: Correlation of two independent observers of the Novel Functional PFM palpation scale; n = 24.

Functional Rating Scale	**0**	**1**	**2**	**3**	**4**	**Kappa with linear weighting**			
0	1	0	0	0	0	Observed Kappa (K_w)	Standard Error (SE)	95% CI Lower Limit	Higher Limit
1	0	2	2	0	0				
2	0	0	1	0	0	**K_w = 0.72**	**SE = 0.10**	**0.53**	**0.92**
3	0	0	0	0	3				
4	0	0	0	3	12				

Table 9.7: Correlation of two independent observers of the Oxford palpation scale; n = 24.

Oxford Rating Scale	**0**	**1**	**2**	**3**	**4**	**5**	**Kappa with linear weighting**			
0	1	0	0	0	0	0	Observed Kappa (K_w)	Standard Error (SE)	95% CI Lower Limit	Higher Limit
1	0	1	0	0	0	0				
2	0	0	1	1	0	0	**K_w = 0.78**	**SE = 0.08**	**0.62**	**0.95**
3	0	0	1	2	1	0				
4	0	0	0	1	7	1				
5	0	0	0	0	2	5				

Table 9.8: Correlation of two independent observers of the Deep palpation scale; n = 24

Deep Rating Scale	**0**	**1**	**2**	**3**	**4**	**5**	**Kappa with linear weighting**			
0	1	1	0	0	0	0	Observed Kappa (K_w)	Standard Error (SE)	95% CI Lower Limit	Higher Limit
1	0	2	1	0	0	0				
2	1	2	6	0	0	0	**K_w = 0.73**	**SE = 0.10**	**0.53**	**0.92**
3	0	0	0	0	0	0				
4	0	0	0	0	6	0				
5	0	0	0	0	0	2				

Table 9.10: Correlation of two independent observers of the Superficial PFM palpation scale; n = 24.

Superficial Rating Scale	0	1	2	3	Kappa with linear weighting			
0	1	0	0	0	Observed Kappa (K_w)	Standard Error (SE)	95% CI Lower Limit	Higher Limit
1	0	0	2	0				
2	0	0	6	2				
3	0	0	2	10	**K_w = 0.62**	**SE = 0.14**	**0.36**	**0.88**

Table 9.11: Results of two independent observers of various vaginal palpation scales

Continence Status	Subject Number	Functional CP	Functional RLJ	Oxford CP	Oxford RLJ	Deep CP	Deep RLJ	Superficial CP	Superficial RLJ
Continent	1	1	2	3	4	4	2	2	3
	2	4	4	5	4	4	4	3	3
	3	4	4	5	5	4	4	3	3
	4	1	2	3	3	2	2	2	2
	5	3	4	4	4	2	2	2	3
	6	4	4	4	4	4	4	3	2
	7	4	4	4	4	5	5	3	3
	8	4	4	4	4	4	4	3	2
	9	4	4	4	4	1	2	3	3
	10	4	4	5	5	4	3	3	3
	11	0	0	0	0	0	1	0	0
	12	3	4	5	4	4	3	3	3
	13	3	4	5	5	2	2	3	3
	14	4	4	5	5	2	2	3	3
	15	4	4	4	5	2	2	3	3
SUI	16	4	4	4	4	4	4	2	2
	17	1	1	2	3	2	2	1	2
	18	1	1	1	1	0	0	2	1
	19	4	3	3	2	2	0	1	2
	20	4	4	4	4	4	4	2	2
	21	4	3	4	3	1	1	2	2
	22	2	2	2	2	1	1	2	2
	23	4	4	5	5	5	2	3	3
	24	4	3	3	3	5	5	2	2

In the Functional, Oxford and Superficial scales, where disagreements existed, they were of only one category. In the Deep scale, on two occasions there were disagreements of two categories, and on one occasion, of three and a tendency for CP to score higher than RLJ, particularly where there was disagreement greater than one category. In the Functional scale, there was a slight bias of CP scoring higher than RLJ in the SUI group, and RLJ scoring higher than CP in the continent group. In the Oxford and Superficial scales, no such bias existed, with RLJ and CP scoring higher or lower 50% of the time across both groups.

9.4.2 Digital examination:

There was a significant difference of parity but not age or BMI of the two groups tested for comparison of digital evaluation of PFM strength and function (Table 9.12).

Table 9.12: Mean and SD of Age, Parity, Body Mass Index (BMI), and Continence Severity Scale (CSS)

	Continent (N = 26)	SUI (N = 10)	P Value
Age	40.8 ± 13.9	46.8 ± 12.9	0.24
Parity	0.4 ± 0.8	1.4 ± 0.8	0.01
BMI	22.4 ± 2.0	25.0 ± 4.1	0.08
CSS	Continent	6 Slightly 4 Moderately	

9.4.2.1 Functional Scale

There was a significant difference between continent and SUI women in their ability to displace the urethra with a voluntary PFM contraction, and support the urethra during a cough (P = 0.001). On average, the PFM of the continent group had at least the ability to produce an obvious displacement of the urethra on all aspects of the palpating finger (mean value 3.5 ± 1.0). The SUI group however had a poor to fair ability to produce displacement of the urethra with a PFM contraction (mean value 1.5 ± 1.0).

9.4.2.2 Oxford Scale

There was a significant difference between continent and SUI women in strength measured digitally (P = 0.01). On average, the PFM of the continent group had a good PFM contraction, able to elevate the examiners fingers against light resistance (mean value

4.0 ± 1.5). The SUI group however had a moderate PFM contraction, producing a slight lift of the examiners fingers (mean value 3.0 ± 1.0).

Inter-observer reliability of detecting specific differences between the right and left sides of the PFM was not assessed; however agreement was reached on whether there was symmetry of contraction between the left and right sides of the PFM in all but one continent subject. With that limitation in mind, there was no significant difference between the left and right side of the PFM in continent women (P = 0.5). In women with SUI, although the difference was not significant, (P = 0.17) the left mean value (2.5 ± 1.0) was higher than the right (2.0 ± 1.5).

9.4.2.3 Superficial Scale:

There was a significant difference between continent and SUI women in displacement of the superficial aspect of the PF measured digitally (P = 0.02). On average, the PFM of the continent group had the ability to produce an obvious to strong squeeze of the proximal part of finger during a PFM contraction (mean value 2.5 ± 1.0), whereas the SUI group had a less obvious squeeze (mean value 2.0 ± 0.5).

9.4.2.4 Deep Scale:

There was a significant difference between continent and SUI women in displacement of the deep aspect of the PF measured digitally (P =0.03). On average, the PFM of the continent group had the ability to produce an inward displacement of the distal part of finger during a PFM contraction with total extension (mean value 3.0 ± 1.0), whereas the SUI group were unable to extend the distal part of the testing finger (mean value 2.0 ± 1.5).

9.5 Discussion:

Inter-observer reliability of various scoring systems will be discussed initially, followed by the differences in digital palpation between continent and SUI women.

9.5.1 Inter-observer reliability:

The study confirmed that various physical examination scales of PFM voluntary contraction can be readily learned between two examiners of different disciplines. The inter-observer agreements obtained in the present study were substantial and consistent with reproducibility scores of other vaginal scoring systems, which vary between (Kw

0.69 to 0.97) (Jeyaseelan *et al.*, 2001;Devreese *et al.*, 2004;Frawley *et al.*, 2006b;Slieker-ten Hove *et al.*, 2008). However the latest study reported by Slieker-ten Hove which conformed to recommendations of the multi-disciplinary Pelvic Floor Clinical Assessment Group (PFCAG) of the International Continence Society (ICS), also indicated poor reliability ($K_w < 0.20$) for 40 % of the vaginal scoring systems chosen (Slieker-ten Hove *et al.*, 2008). The Functional Scale, proposed by the author, had a weighted $K_w = 0.72$, CI 0.53 to 0.92, and its reliability was in line with that of the more familiar Oxford Scale. There existed a small systematic bias in reliability testing of the Functional Scale, which may be possible to improve with further training, or by reducing the measurement categories to a four point scale such as Table 9.12.

Table 9.12: Suggested modified functional scale of PFM contraction

Grade	Description
0	Absent: not present
1	Present: able to feel vague sensation on the palpating finger
2	Good: obvious sensation of displacement on all aspects of palpating finger
3	Functional: able to maintain displacement on cough

The suggested modified scale, which the author currently uses in her clinical practice, is probably adequate for clinicians working with Urinary Incontinence and especially useful for those without access to an ultrasound machine. However, for scientific purposes, an ordinal scale with less than five categories may not have sufficient sensitivity to differentiate between individuals, and consequentially may be compromised by the statistics necessary to analyse it.

The Superficial Scale indicated slightly lower reliability between examiners, (weighted K_w =0.62, and CI of 0.36 to 0.88), although it was still rated substantial by criteria defined by Landis and Koch (Landis & Koch, 1977). The slightly lower reliability could be due to the smaller number of categories within the scale or perhaps the absence of a readily identifiable landmark from which to place the finger compared to both the Deep and Functional scales. It could be argued that the Oxford Scale also has a less distinguishable landmark in which to consistently place the finger, so its higher reproducibility may also be reflective of the higher number of categories within the scale or the familiarity of the test, since both examiners routinely use this scale in their clinical practice.

Inter-observer agreement of the Oxford scale (weighted K_w =0.78, and CI of 0.62 to 0.95), was in line with two other studies evaluating reliability (K_w 0.69 to 0.86). (Jeyaseelan *et al.*, 2001;Frawley *et al.*, 2006b) and indicated substantial agreement The one study that has previously concluded that the method was not reproducible, sensitive and valid to measure PFM strength for scientific purposes, was based on the results of Spearmans $r = 0.70$ $p < 0.01$ and un-weighted Kappa statistic of $K = 0.37$ (S.E.M = 0.16) (Bo & Finckenhagen, 2001). As discussed earlier in Chapter 2 Section 2.8, neither statistical test used by Bo et al is optimal for judging reliability of the Oxford scale. The multidisciplinary group of the PFCAG suggested that the quantification of a voluntary PFM contraction was problematic and recommended the use of a four point scale, absent, weak, normal or strong (Messelink *et al.*, 2005) (Chapter 2, Section 2.8, Table 2.2). Testing this scale for reliability (Slieker-ten Hove *et al.*, 2008) indicated that a voluntary contraction of PFM had an intra-observer and inter-observer agreement of K_w = 0.67, (95% CI 0.46 to 0.81) and K_w = 0.64 (95% CI 0.48 to 0.77) respectively, which is slightly poorer than all the Oxford Scale reliability studies that have been reported using the appropriate statistics.

A pragmatic approach was taken to evaluate the reliability of testing symmetry of PFM contraction in this current study. Rather than producing ordinal data from evaluation of the left and right sides of the PFM, it was decided to evaluate only whether there was symmetry between sides. This practical choice was undertaken because the uro-gynaecologist (CP) in this current study did not routinely measure left and right sides of the PF in addition to personal communication with Devreese in 2002 who suggested that even after extensive discussion, testing and training, acceptable inter-observer agreement for symmetry could not be attained in their pilot studies. Poor inter-observer variability for symmetry of contraction has subsequently been reported (K_w = 0.16) (Slieker-ten Hove *et al.*, 2008).

The PFCAG had suggested that other qualities of PFM function such as voluntary relaxation after contraction, involuntary contraction and relaxation of the PFM during an increase in intra-abdominal pressure (IAP) such as a cough should also be verified as part of a clinical assessment. Although intra-observer reliability was shown to be fair to good for some categories such as the presence of pain, or voluntary activation of the PFM(K_w = 0.33 to 0.76), inter-observer reliability was poor for palpation and movement of the perineum during a cough (K_w = 0.03 and 0.01 respectively) (Slieker-ten Hove *et al.*, 2008).

The Deep and Superficial scales have not been tested for reliability since Devreese et al published in 2004 (Devreese *et al.*, 2004). Even though the study by Devreese et al had 40 volunteers within each group, this current study indicates very similar values of inter-observer reliability of the Deep scale: K_w = 0.73, CI 0.53 to 0.92 compared to K_w = 0.77, CI 0.61 to 0.95. However the reliability of the Superficial scale in this current study was lower: K_w = 0.62, CI 0.36 to 0.88 compared to K_w 0.75, CI 0.64 to 0.87.

9.5.2 Differences in digital palpation between groups:

Within all palpation scales, there was a significant difference in digital evaluation of strength and PFM function between continent women and women with SUI. These findings support a number of studies that have identified decreased PFM strength (Gunnarsson & Mattiasson, 1999); (Morkved *et al.*, 2004), endurance (Deindl *et al.*, 1994) thickness (Bernstein, 1997;Morkved *et al.*, 2004) and displacement (Devreese *et al.*, 2004) in women with incontinence. However, as discussed earlier, there are many women with a strong PFM who have SUI, and conversely a number of continent women who have a weak pelvic floor, indicating that there are other mechanisms than muscle strength that play a role in maintaining continence.

The latest Cochrane review suggested that even though PFM rehabilitation improved continence function, other qualities of PFM function that were not measured might contribute to the improvement in incontinence, such as timing of PFM contraction (Dumoulin & Hay-Smith, 2008). Certainly a well timed PFM contraction is an important skill, since “the Knack” has been shown to be an effective treatment for women with SUI (Miller JM *et al.*, 1997). The Functional Scale is a novel measurement of PFM function that measures this skill and in addition it gauges whether or not a voluntary PFM contraction can support the urethra during a cough, irrespective of strength, pathology, position of the pelvic organs, or co-ordination with other muscles of the lumbo-pelvic cylinder.

To provide independent validity of the Functional measurement scale, it would have been of additional value to have seen whether there was any correlation between the Functional Scale and urethral or vaginal pressure measurement. Urethral and vaginal pressures have been shown to correlate significantly during PFM contraction yet it is reported that 46% of women who correctly contract their PFM fail to increase intra-urethral pressure.

From statistics generated from this feasibility study, power analysis suggests that a sample size of only 12 women in each group would have an 80% power to detect a difference of similar means with a significance level (alpha) of 0.05 (one-tailed). However this current study does not address matters of test-retest reliability, responsiveness and sensitivity to change which would need to be addressed in a future study before the absolute usefulness of the Functional scale could be determined.

9.6 Conclusions:

The Functional Scale is a simple, reliable digital palpation scale that distinguishes between continent women and women with SUI. It measures whether or not a voluntary PFM contraction causes a squeeze and inward lift of the PFM, with resultant urethral stabilization, and resistance to downward movement during a cough. This study indicated that the strength, displacement and function of the PFM differ between continent and SUI women and these differences can be reliably measured with digital palpation by examiners of different disciplines.

In the next chapter, displacement values of the ano-rectal angle (ARA) and urethra during a PFM contraction will be calculated using TP ultrasound and image processing methods. Following that, the displacement values will be compared to the various palpation scales, in order to test both the validity of the image processing methods and the Functional Scale proposed by the author.

10 Effect of a Voluntary Pelvic Floor Muscle (PFM) Contraction on the Pelvic Floor; Evaluated by Real Time Ultrasound and Image Processing Methods (IPM).

10.1 Introduction

As discussed in the previous chapter, an ideal conscious, voluntary pelvic floor muscle (PFM) contraction would cause a squeeze and inward lift of the PFM, with resultant urethral closure, stabilization, and resistance to downward movement during rises in intra-abdominal pressure (IAP) (Delancey, 1988). However it has been reported that only 36–49% of women with incontinence and prolapse can produce a correct PFM contraction with 25–39% of subjects using a significant Valsalva or straining effort (Bump *et al.*, 1991;Theofrastous *et al.*, 1997;van Loenen & Vierhout, 1997). Pelvic floor (PF) depression has also been observed in 43% of women with incontinence and prolapse when attempting to elevate the PFM in a study using transabdominal (TA) ultrasound (O'Sullivan *et al.*, 2002;Thompson & O'Sullivan, 2003;Sherburn *et al.*, 2005).

Current transperineal (TP) measurements of a voluntary PFM contraction using 2D ultrasound imaging quantify the cranio-ventral displacement of the bladder neck (BN) at rest, in relation to the position at the end of the contraction relative to the symphysis pubis (SP). In TA imaging, there is no fixed reference point and displacements are taken with on screen callipers from a position on the bladder base (BB) at the point of greatest excursion (Chapter 2, Section 2.11). Any method relying on a change in the position or geometry of the BB or BN may be limited in those who have a pelvic organ prolapse (POP) interfering with BN motion or who have undergone a surgical procedure aimed at immobilizing the BN (Peschers *et al.*, 2001b).

In order to achieve a more direct measurement of PFM contraction using 2D ultrasound imaging, Costantini et al indicated that the anorectal junction is pulled forward towards the SP and the ano rectal angle (ARA) closes during a PFM contraction (Thompson & O'Sullivan, 2003;Costantini *et al.*, 2006;Weinstein *et al.*, 2007;Braekken *et al.*, 2009). More latterly, three studies using 3D ultrasound have also measured a significant reduction in hiatal sagittal diameter measuring from ARA to the SP during a PFM voluntary contraction (Thompson & O'Sullivan, 2003;Verhey *et al.*, 2005;Dietz *et al.*, 2005;Costantini *et al.*, 2006;Dietz *et al.*, 2006;Weinstein *et al.*, 2007;Huang *et al.*, 2007;Kruger *et al.*, 2008;Yang *et al.*, 2009;Braekken *et al.*, 2009). A clinical observation using ultrasound imaging is that the direction of PFM contraction from the ARA varies between subjects (personal communication Maeve Whelan 2001). Occasionally, instead of providing a cranio-ventral displacement of the BN and urethra, the PFM contraction produces a more acute "vaginal" contraction with little ventral displacement, or can displace the posterior bladder wall rather than the urethra.

There is disagreement about whether a PFM contraction is more effective in standing or supine as some TA ultrasound studies suggest that there is greater elevation of the PF in standing (Kelly *et al.*, 2007;Frawley *et al.*, 2006a) whereas another study using TP ultrasound suggest better contractions in supine (Dietz & Clarke, 2001a). As discussed earlier (Chapter 2 Section 2.11), the amount of displacement during a conscious muscle contraction may not be a sensitive measure of PFM function as smaller displacements could be representative of higher resting tone in the PFM musculature and/or poor voluntary contraction of the PFM, whereas larger displacements could be due to a stronger PFM contraction, or increased laxity in the connective tissue. As a consequence,

This chapter evaluates the displacement of the ARA and urethra measured with 2D ultrasound and image processing methods during a voluntary PFM contraction in supine and standing, accounting for the relative starting positions of the PF structures as determined in Chapter 7. The subsequent chapter will assess the validity of the image processing methods and the Functional Scale of PFM measurement.

10.2 Aim

To quantify the effect of a voluntary PFM contraction in supine and standing on the ARA and urethra using 2D transperineal (TP) ultrasound and IPM, comparing the response between continent and SUI women.

10.3 Hypothesis

There is greater cranio-ventral displacement of the ARA and urethra in the continent compared to the SUI group during a maximum perceived voluntary PFM contraction in standing.

10.4 Methods:

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3.

Thirty three (33) female volunteers were asked to perform three consecutive slow maximum perceived voluntary contractions (MPVC) with a 5 second hold then release, with a 5 second rest in between. Instructions to the volunteer to elicit a PFM contraction followed International Continence Society (ICS) guidelines:

"Squeeze the muscles of the pelvic floor as if attempting to stop the flow of urine or prevent wind or flatulus escaping" with the addition of "squeeze around the back passage, as if you were trying to prevent breaking wind (flatus); bring that feeling forward towards the urethra/pubic bone and then lift, as if you were elevating the PFM, whilst breathing normally".

Volunteers were positioned in supine crook lying with one pillow under their head and if time allowed, in relaxed standing, with their feet hip width apart. Verification of the ability to perform a correct PFM contraction was assessed during digital vaginal examination, which was always performed prior to ultrasound recordings in order to minimise any bias gained from the operator observing the ultrasound images.

10.4.1 TP ultrasound, image processing methods and graph alignment:

Application of the ultrasound transducer (Section and 6.4.1); segmentation methodology for the urethra and relative position of the urogenital structures (Sections 4.4, 6.4.2 and 7.3.1); motion tracking algorithms for the symphysis pubis (SP) and ARA (Section 4.3, 6.4.2); have already been described. Graph alignment is at the start of the PFM contraction.

10.4.2 Statistical analysis:

Mean and Standard Error (SE) of the displacement was calculated and presented graphically. Statistical comparisons using one-tailed unpaired T-test, were performed on the average of the three consecutive contractions, to evaluate the mean maximum displacement values (± 2SD) and level of significant difference between groups and to compare the effects of a change, between standing to supine within each group. Welch's correction was applied where the variances were unequal, and a level of $P < 0.05$ was considered significant.

10.5 Results

One volunteer was excluded due to symptoms of overactive bladder (OAB) and was excluded from the ultrasound analysis. ARA and urethral displacements were normally distributed in both the supine and standing positions. The displacement of the urethra and ARA in twenty two (22) continent women were analysed in supine, and sixteen (16) in standing. Nine women with SUI were analysed in supine, five in standing.

10.5.1 Supine displacement:

In response to a maximum perceived voluntary contraction (MPVC), the ARA and urethra of both groups were displaced in a cranio-ventral direction (Figure 10.1, 10.2).

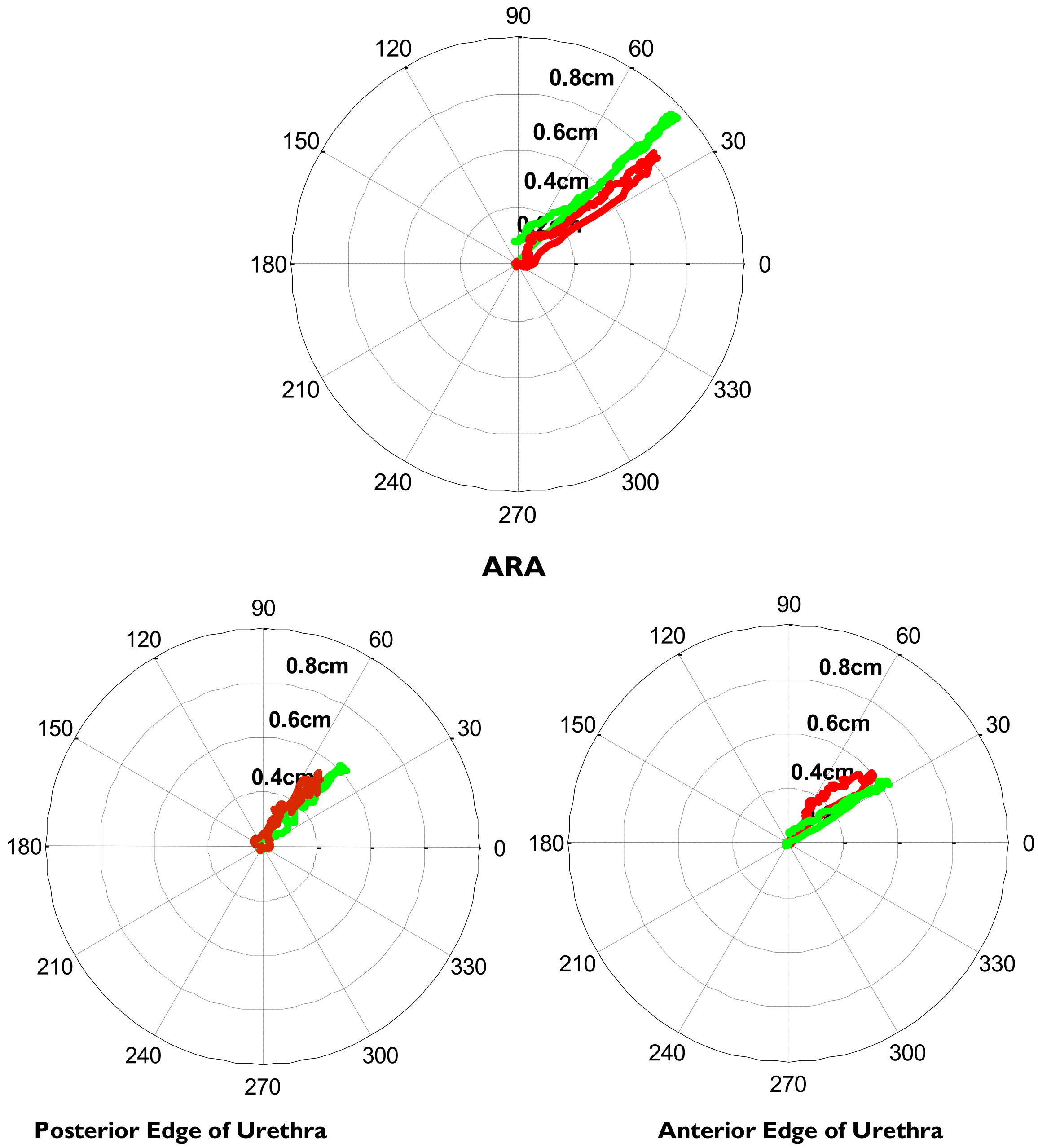


Figure 10.1: A comparison of the cranio-ventral displacements of the ARA, posterior and anterior edges of the urethra during a voluntary PFM contraction in supine: continent (n= 22; green line) and SUI (n= 9; red line). The shaded area represents the SE.

From a zero reference point, the amount of overall displacement was slightly bigger in the continent group, but this did not reach statistical significance in any direction (Table 10.1). However the direction or angle of displacement of the posterior edge of the urethra was different between groups, with the more acute displacement occurring in the continent group.

Table 10.1: Mean and SD of the maximum displacements of ARA and urethra during a voluntary PFM contraction in supine (mean ± SD, Unit: cm; Angle: degrees). (UV = Welch's correction applied for unequal variances)(ARA; Continent n = 23 and SUI n = 9: Urethra; Continent n = 23 and SUI n = 9).

	Ventral	**Cranial**	**Resultant**	**Angle (degrees)**
ARA				
Continent	0.67 ± 0.38	0.58 ± 0.27	0.82 ± 0.41	45 ± 16
SUI	0.57 ± 0.32	0.49 ± 0.21	0.70 ± 0.34	40 ± 13
P Value	NS P = 0.31	NS P = 0.18	NS P = 0.23	NS P = 0.32
Posterior				
Continent	0.39 ± 0.22	0.43 ± 0.16	0.60 ± 0.25	48 ± 15
SUI	0.27 ± 0.19	0.42 ± 0.23	0.52 ± 0.22	57 ± 14
P Value	NS P = 0.09	NS P = 0.45	NS P = 0.20	**P = 0.05**
Anterior				
Continent	0.43 ± 0.22	0.32 ± 0.14	0.56 ± 0.22	35 ± 14
SUI	0.37 ± 0.21	0.37 ± 0.26	0.56 ± 0.26	45 ± 22
P Value	NS P = 0.26	NS P = 0.26 (UV)	NS P = 0.50	NS P = 0.16

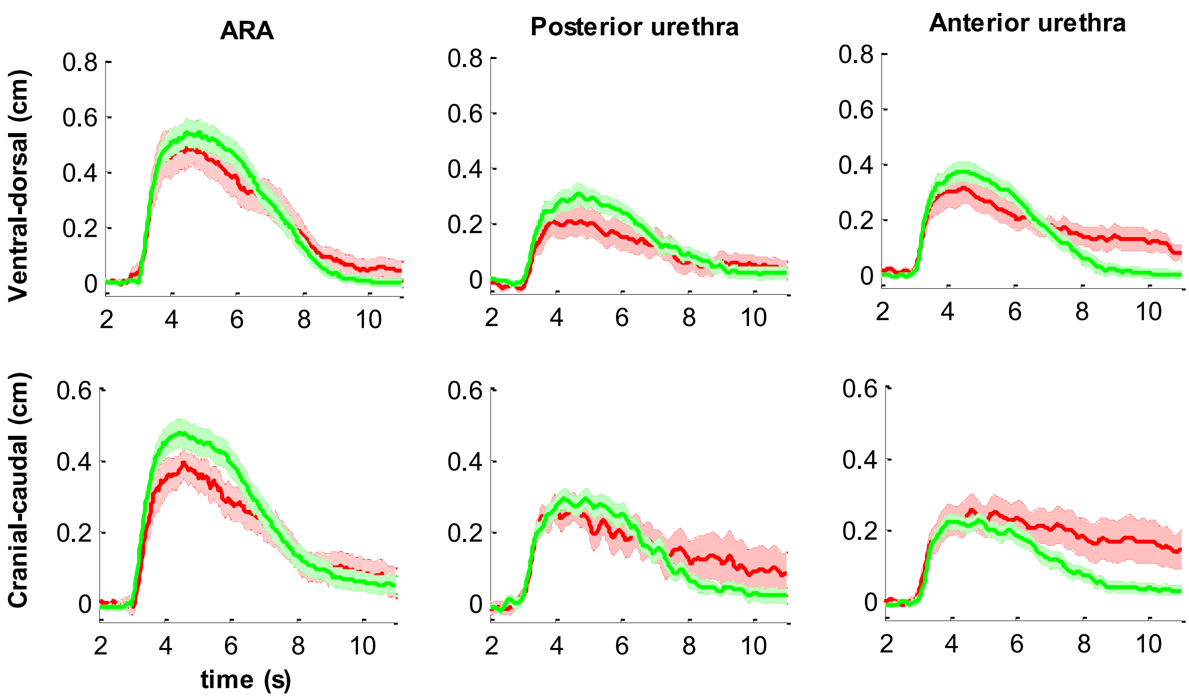


Figure 10.2: A comparison of the dorso-ventral and caudo-cranial displacements of the ARA, posterior and anterior edges of the urethra during a voluntary PFM contraction in supine: continent (n= 22; green line) and SUI (n= 9; red line). The shaded area represents the Standard Error.

10.5.2 Standing displacement:

From a zero reference point, in standing there were significantly larger cranio-ventral displacements of both the ARA and urethra in continent women than those with SUI (Figures 10.3, 10.4, Table 10.3).

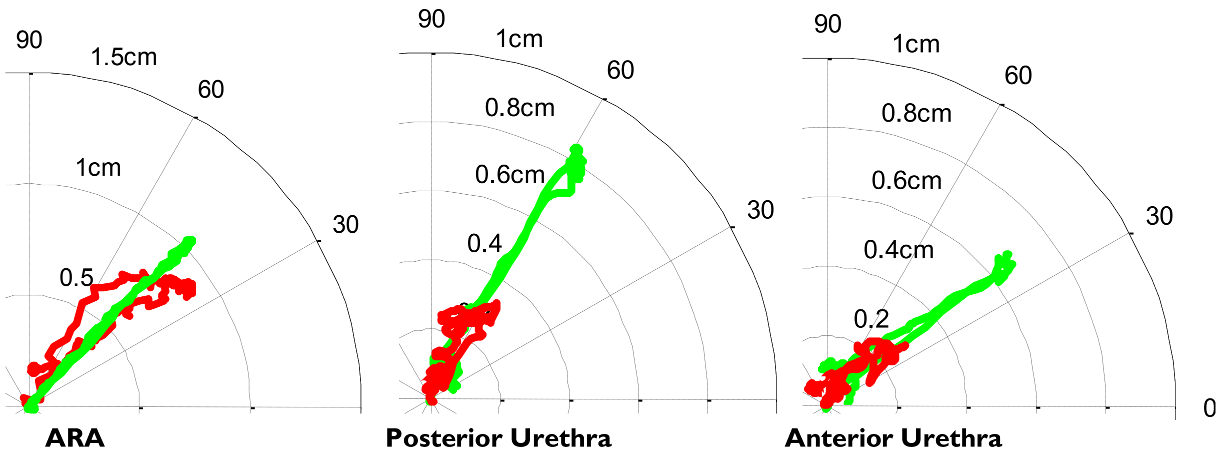


Figure 10.3: Comparison of the mean displacements of the ARA, and both edges of the urethra during a PFM contraction in standing in continent (ARA n = 16; urethra n = 5; green line) and SUI (ARA n = 5; urethra n = 5; red line) women.

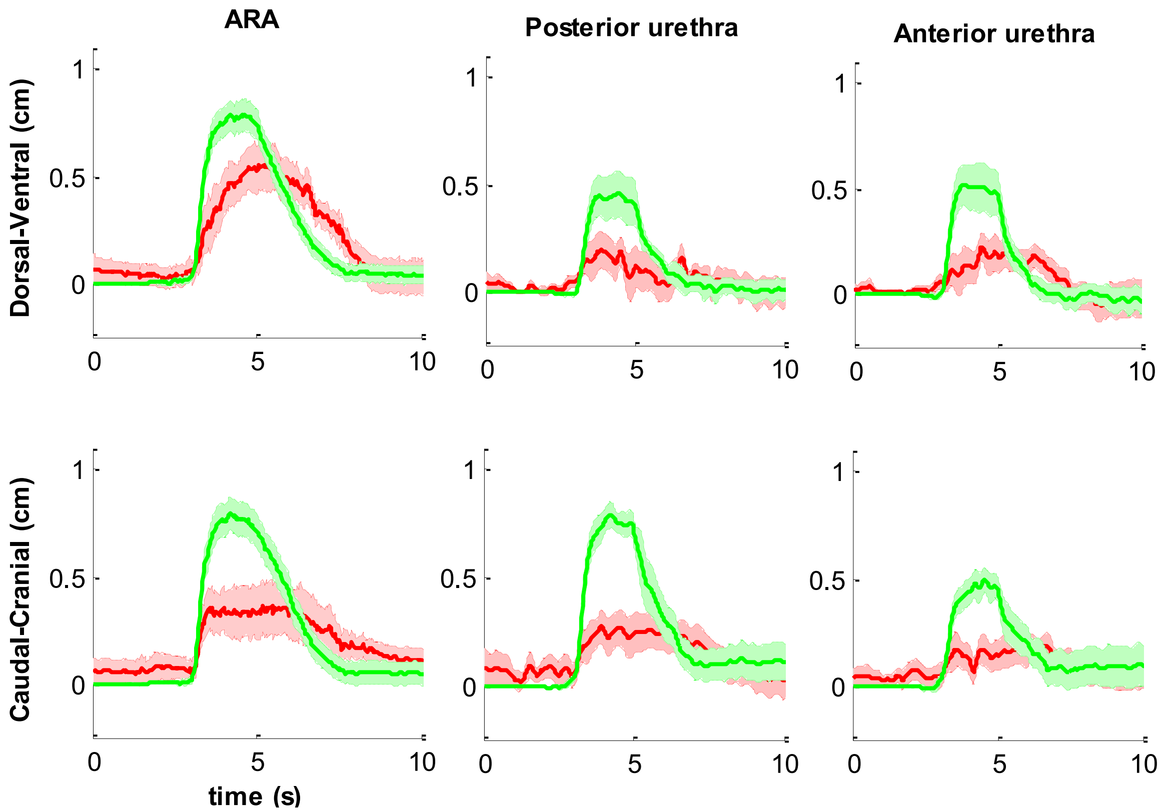


Figure 10.4: A comparison of the dorso-ventral and caudo-cranial displacements of the ARA, posterior and anterior edges of the urethra during a voluntary PFM contraction in standing: continent (ARA n = 16; urethra n = 5; green line) SUI (ARA n = 5; urethra n = 5; red line). The shaded area represents the Standard Error (SE).

Although the overall resultant displacements of the ARA and urethra were significantly greater in the continent group, in general, the cranial component of the displacements indicated the biggest differences (Table 10.2). There was over twice as much overall resultant displacement of the urethra in the continent group, and in addition, the anterior edge of the urethra also showed significant differences in the ventral displacement. There were no significant differences in the direction or angle of displacement (Table 10.2, Figure 10.3).

Table 10.2: Mean and SD of the maximum displacements of ARA and urethra during a voluntary PFM contraction in standing (mean ± SD, Unit: cm; Angle: degrees). (ARA; Continent n = 16 and SUI n = 9: Urethra; Continent n = 5 and SUI n = 5).

	Ventral	**Cranial**	**Resultant**	**Angle (degrees)**
ARA				
Continent	0.79 ± 0.42	0.82 ± 0.39	1.2 ± 0.47	48 ± 18
SUI	0.58 ± 0.26	0.40 ± 0.25	0.72 ± 0.40	39 ± 14
P Value	NS P = 0.17	**P = 0.026**	**P = 0.038**	NS P = 0.18
Posterior				
Continent	0.48 ± 0.24	0.82 ± 0.14	0.97 ± 0.21	61 ± 10
SUI	0.23 ± 0.18	0.34 ± 0.13	0.40 ± 0.24	61 ± 18
P Value	NS P = 0.053	**P = 0.002**	**P = 0.001**	NS P = 0.49
Anterior				
Continent	0.58 ± 0.26	0.52 ± 0.26	0.81 ± 0.27	41 ± 20
SUI	0.25 ± 0.26	0.25 ± 0.10	0.37 ± 0.23	54 ± 22
P Value	**P = 0.037**	**P = 0.044**	**P = 0.012**	NS P = 0.18

10.5.3 Comparison of supine to standing displacements:

From a zero reference point, in the continent group, there was significantly more displacement of the ARA and urethra in standing than in supine (Tables 10.1, 10.2). ARA (1.2 ± 0.47cm: 0.82 ± 0.41cm: P =0.03), posterior edge (0.97 ± 0.21cm: 0.52 ± 0.22: P= 0.007) and anterior edge (0.81 ± 0.27cm: 0.56 ± 0.22: P= 0.01). However in the SUI group, there was a slight decrease in the amount of displacement in standing compared to the supine position, but this was not significant. ARA: (0.72 ± 0.40cm : 0.70 ± 0.34cm); posterior edge (0.40 ± 0.24cm: 0.52 ± 0.22 cm) (0.37 ± 0.23: 0.56 ± 0.26 cm) anterior edge.

However, when accounting for the relative starting positions of the PF structures, the differences between groups and the effect of a change in posture on the PF structures became clearer (Figure 10.5). Although the ARA and urethra of the continent group were displaced more in standing than supine from a zero reference point, due to the lower starting position in standing, neither structure reached as high a cranio-ventral position in standing as they did in supine. Similarly from supine to standing, the PF structures of the SUI group dropped so far caudally, that the end position of a maximum PFM contraction in standing, failed to even reach the supine starting position.

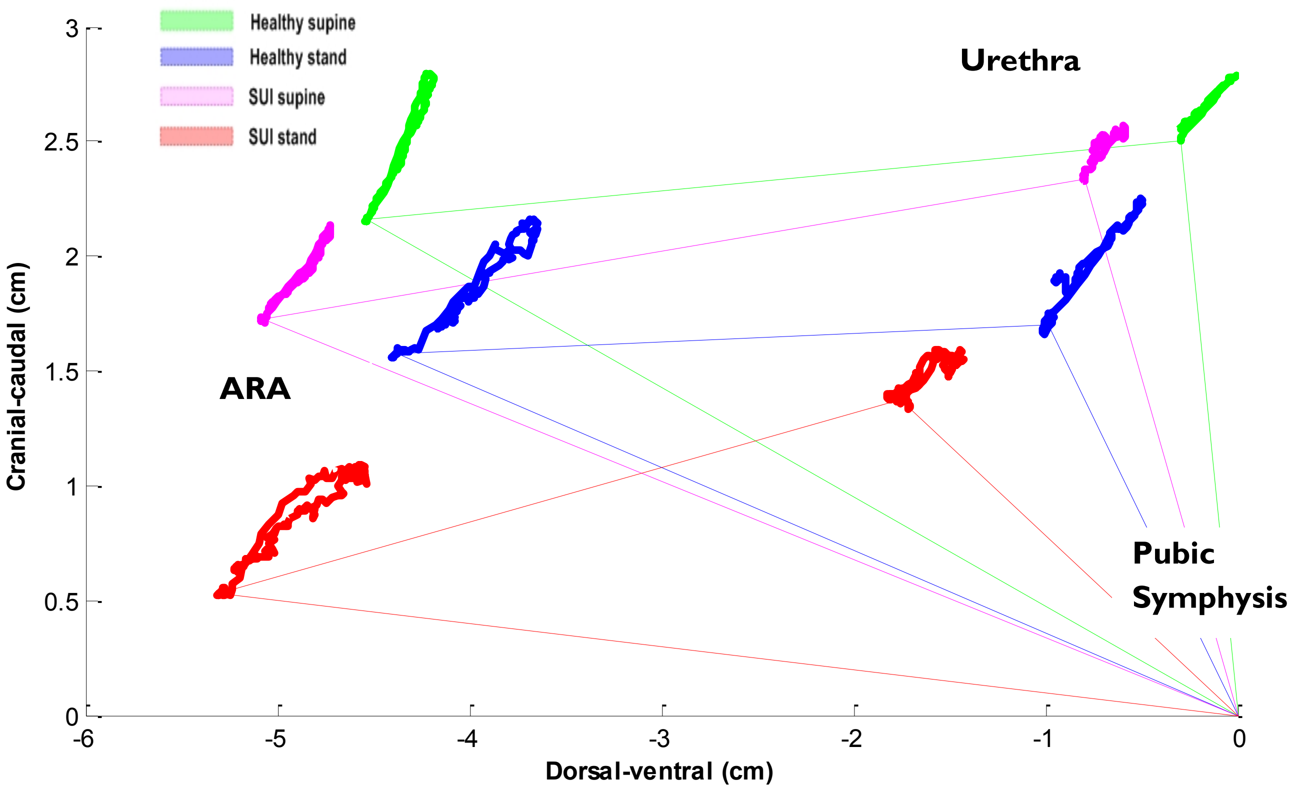


Figure 10.5: The relative starting positions and average trajectories of the urethra and ARA during a PFM contraction in supine and standing: (green line continent supine n = 22: blue line continent standing n = 16: pink line SUI supine n=9: red line SUI standing n=5).

10.6 Discussion:

Using 2D TP ultrasound imaging combined with image processing methods (IPM), novel information about the displacement of the ARA and urethra during a PFM contraction was quantified. From a zero reference point, there were significant differences in the amount of displacement of both the urethra and ARA between continent and SUI women in standing, however no significant differences in the amount of displacement in supine, although the direction or angle of displacement of the posterior edge of the urethra was more acute.

When the relative starting positions were not accounted for, the lack of significant differences between groups in supine is consistent with other ultrasound studies assessing the effect on the BN or urethra-vesical junction (UVJ) measured relative to the central axis of the SP in continent and incontinent women (Wijma *et al.*, 1991;Thompson *et al.*, 2005). Thompson et al 2005 also found that there was no difference in displacement values between parous and nulliparous groups which is in contrast to previous studies which concluded that childbirth reduces bladder neck displacement on PFM contraction (Peschers *et al.*, 1997b;Dietz, 2004). The study by Thompson et al indicated smaller and more variable displacement values compared to this current study, which is more in line with the studies by Wijma et al 1991, Peschers et al 1997 and Dietz 2004.

Again, not accounting for starting position, continent women had significantly greater displacements in standing compared to the supine position, which is in agreement with other studies using TA ultrasound to measure the displacement of the BB (Frawley *et al.*, 2006a;Kelly *et al.*, 2007). However Kelly et al mistakenly concluded that the greater displacement in standing represented a greater ability of healthy adults to elevate the PF in standing compared to supine. This current study clarifies that the greater displacement in the standing position does not reflect an anatomically higher final resting position of either the ARA or urethra and is representative of the ARA and urethra starting from a lower position, due to the effects of gravity on the pelvic viscera (Figure 10.5). Accounting for the relative starting position of the PF structures, this current study is in agreement with the earlier study using TP ultrasound by Dietz et al which indicated that there were better contractions in supine (Bump *et al.*, 1991;Dietz *et al.*, 2001;Thompson & O'Sullivan, 2003). Furthermore, using TA ultrasound, although Frawley et al also measured greater displacements in standing, they measured lower digital and squeeze-pressure readings in an upright compared to the supine position (Frawley *et al.*, 2006a). This current study emphasises the caution required when interpreting larger displacements as stronger PFM contractions or conversely smaller displacements representing poorer voluntary contractions of the PFM. In SUI women, even from a zero reference position, there were smaller displacements of the ARA and urethra in standing compared to the continent group. It appears that women with SUI are less able to overcome the weight of pelvic organs and the effects of gravity on the PFM than continent women. It may be more difficult for the PFM to generate further contractility upon a pre-loaded or pre-activated base, and emphasises the need to also rehabilitate the PFM of SUI women in standing. It should also be emphasised then, that since the woman with SUI will find it more difficult to activate their PFM in standing to the inner range of contraction, she should first rehabilitate in lying, progressing to a standing position.

In this current study, there were significant differences between the displacement angle of the posterior edge of the urethra between groups, and significant differences in the direction of urethral displacement between the anterior and posterior edge in continent women. Clinically, observations of subtle differences in the direction of urethral and ARA displacement have seemed relevant when using manual therapy and facilitation techniques to the PFM. Using manual therapy techniques, as long as there was not significant tearing or laxity of the connective tissue structures, the direction and magnitude of voluntary contractions could appear to change rapidly, within minutes of treatment intervention, sufficiently to displace and directly support the urethra. However, if there is significant tearing of the connective tissue structures, a PFM contraction is unlikely to be able to have the appropriate anatomical construction to compress the urethra, irrespective of its strength, and conservative treatment is unlikely to succeed. However this current study shows that it is possible to measure the angles of displacement, and may be a potential outcome measure, for a future intervention study. Although an 80% power calculation suggests that in supine a sample size of 100 in each group would be required to detect a difference between the mean displacements of the posterior edge of the urethra of 0.08 cm with a significance level (alpha) of 0.05 (one-tailed), only 20 in each group are required if the angle of displacement is used.

There are many reports in the literature that cite the inability of women to correctly activate their PFM on command, up to 30% at their first consultation and even after thorough individual instruction (Bump *et al.*, 1991;Kegal, 1948;Benvenuti *et al.*, 1987;Bo *et al.*, 1988). A study of 120 women using TA ultrasound indicated that 43% of women with incontinence and prolapse depressed the BB when attempting to elevate the PFM (O'Sullivan *et al.*, 2002;Thompson & O'Sullivan, 2003;Sherburn *et al.*, 2005). In a later study using a TP approach, BN depression also occurred in 17% of continent and 30% of incontinent women with a voluntary PFM contraction (Thompson *et al.*, 2006b). Yet in a more recent study involving 209 women, only six (3%) were unable to contract their PFM under detailed instruction (Yang *et al.*, 2009). Only one woman in this current study, who was nulliparous and continent, had an inability to perform an elevating PFM contraction. In this current study, digital palpation prior to the ultrasound verified that the volunteer could perform a correct PFM contraction, and it is possible that this helped to facilitate a correct activation; however, it was clear to the examiner (RLJ) that no other volunteer required facilitation and was able to correctly contract their PFM immediately. Although this finding could just be due to the small numbers within the study group, it may be worth further investigation. Perhaps the study population was more aware of how to correctly activate their PFM, or perhaps the verbal command, with an emphasis of involvement of the ARA; to bring the contraction from back to front was clearer than just an emphasis on stopping the flow of urine. In future studies, it would be useful to determine whether the inability of the volunteers to correctly activate their PFM is due to the volunteer, the instruction or the measurement method.

This study did not quantitatively address the ability to fully relax the PFM, nor did calculate the endurance of the PFM contraction. However both qualities of PFM functions could easily be incorporated into future studies. It was interesting to observe that in supine in the SUI group, the wave form did not return to the starting position (Figure 10.2) whereas the continent group did. In standing, both groups returned to the starting position (Figure 10.4). This could be representative of the ability to relax the PFM however may also be due to the limitations in the technical aspects of the study in the respect of the synchronisation method, and/or the definition of the start and end point of a manoeuvre (Chapter 5, Section 5.2.2.2).

10.7 Conclusions:

2D TP ultrasound combined with IPM is able to detect significant differences between the amount of displacement of the ARA and urethra in continent and SUI women when performing a voluntary PFM contraction in standing, although these differences are not significant in supine. The implication for future work is that during intervention studies, the standing position should be used in rehabilitation of women with SUI.

This current study emphasises the caution required when interpreting larger displacements as stronger PFM contractions or conversely smaller displacements representing poorer voluntary contractions of the PFM. A larger displacement on ultrasound does not imply an anatomically higher final resting position of either the ARA or urethra. Caution regarding the interpretation of the amount of ARA or urethral displacement, particularly without access to a fixed reference point or accounting for the relative starting positions of PF structures is warranted.

In Chapter 9, digital examination of the PFM using various scales was found to have substantial inter-observer reliability. A new scale of PFM measurement, the

Functional Scale was proposed and seen to be both reliable and feasible. In order to validate the IPM and the Functional Scale, the following chapter will compare the displacements quantified using IPM during a voluntary PFM contraction to the findings from the physical examination.

11 Validity of Image Processing Methods: Correlation of Ultrasound Displacement with Digital Examination

11.1 Introduction:

In previous chapters, it was determined that 2D transperineal (TP) ultrasound combined with image processing methods (IPM) was a reliable measurement technique which was also able to detect significant differences between continent and women with stress urinary incontinence (SUI). However, in order to determine the validity of 2D TP ultrasound combined with IPM as a measurement method, it needs to be compared to another measurement tool, ideally one which is regarded as a 'gold standard'.

Digital muscle palpation performed vaginally or per rectum, is currently considered the gold standard for PFM evaluation (Peschers *et al.*, 2001b), although reliability is called into question by some authors (Bo & Talseth, 1996;Bo & Finckenhagen, 2001). As discussed in Chapter 2, suitable instrumentation for the PF, such as manometers, are currently limited, particularly due to the potential of false-positive measurements as a result of trick manoeuvres (Bump *et al.*, 1996;Morkved & Bo, 1997;Peschers *et al.*, 2001b). However the recent development of a reliable dynamometer may in the future provide a commercially available instrument that may become a more acceptable gold standard compared to digital palpation, since it is more quantitative and reduces the degree of physical interaction between the assessor and patient (Dumoulin *et al.*, 2003;Dumoulin *et al.*, 2004a;Morin *et al.*, 2004a;Morin *et al.*, 2004b). The development of a multi-directional intra-vaginal probe discussed in the subsequent chapter (Chapter 12) may also become such a tool, but as yet the reliability of the novel intra-vaginal probe has not been ascertained.

Correlation of ultrasound parameters with digital palpation strength varies markedly in reports using different approaches. TP ultrasound demonstrated fair to good correlations of digital palpation strength using the modified Oxford scale during voluntary PFM contraction with a variety of ultrasound parameters, such as various changes in urethral angle and overall displacement of the bladder neck (BN) ($r = 0.52$ to 0.62) (Dietz *et al.*, 2002). Displacement of the BN had best agreement which also improved when 7 patients with surgical procedures designed to immobilise the BN were removed from the analysis ($r = 0.62$ to 0.66). Thompson et al (Thompson *et al.*, 2005;Thompson *et al.*, 2006b) also correlated strength of PFM contraction measured by Oxford scale with overall ultrasound displacement of the BN measured with TP ultrasound imaging and bladder base (BB) motion using transabdominal (TA) ultrasound. Both studies indicated a statistically significant fair to good correlation co-efficient ($r = 0.49$ (BB) and 0.58 (BN)). However also using TA ultrasound, another study found no association between digital palpation strength and BB motion, either in a transverse or sagittal plane ($r = 0.21$ and -0.13) respectively (Sherburn *et al.*, 2005), which was also supported in a study using transvaginal (TV) ultrasound measurements in 209 women with urinary incontinence ($r = 0.19$) (Yang *et al.*, 2009) . Yang et al also measured various vector lengths between the BN, anorectal angle (ARA) and symphysis pubis (SP) including sagittal hiatal diameter between the SP and ARA (Yang *et al.*, 2009). The only ultrasound parameter to have a significant correlation with PFM contraction measured using the modified Oxford scale was shortened sagittal hiatal diameters, which indicated a statistically significant, negative fair correlation ($r = -0.348$, $P < 0.001$). Dietz et al using 3D/4D TP ultrasound, also indicated that average Oxford grading was weakly associated with reduction in hiatal dimensions on PFM contraction ($r = -0.32$, $P = 0.024$), but it is unclear in which plane the dimensions were measured (Dietz *et al.*, 2006).

There is a question as to whether a larger displacement on ultrasound imaging implies a stronger PFM contraction. As discussed earlier, the confounders are that larger displacements could be due to a stronger PFM contraction, or increased laxity in the connective tissue, or a lower starting position. Conversely, smaller displacements could be representative of higher resting tone in the PFM musculature, poor voluntary contraction of the PFM or a higher starting position.

In Chapter 9, digital examination of a voluntary PFM contraction, using a variety of ordinal scales, was both repeatable and able to distinguish between continent and SUI women. In Chapter 10, 2D TP ultrasound combined with IPM was able to detect significant differences between the amount of displacement of the ARA and urethra in continent and SUI women when performing a voluntary PFM contraction in standing, although these differences were not significant in supine. This chapter discusses the strength of association between the displacement of the ARA, measured by speckle tracking, and urethra, measured by segmentation, with two validated scales of digital physical examination, the Oxford Scale (Laycock & Jerwood, 2001) and the Deep and

Superficial Scale (Devreese *et al.*, 2004), and the Functional Scale proposed by RLJ in Chapter 9.

11.2 Aims

11.2.1 To validate urethral and ARA measurements taken with 2D TP ultrasound combined with IPM.

11.2.2 To validate the Functional Scale digital evaluation of PFM function using comparisons with 2D TP ultrasound imaging combined with IPM.

11.2.3 To establish whether the correlation between digital examination and ultrasound measurements is comparable for subgroups of continent and SUI women.

11.2.4 To correlate the two IPM displacements measured by speckle tracking of the ARA and segmentation of the urethra during a voluntary PFM contraction.

11.3 Methods:

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3.

Thirty three (33) women received a structured physical digital examination by RL along with acquisition of the ultrasound images. The ultrasound evaluation was always performed after the physical examination in order to minimise any bias gained by observing the ultrasound images. The methods and results of the digital examination during a voluntary PFM contraction were reported in Chapter 9, and acquisition and data processing of the ultrasound images were reported in Chapter 10.

11.3.1 Statistical analysis:

Comparisons between the various digital scales and displacement of the ARA measured by speckle tracking and displacement of the urethra measured using segmentation were evaluated by Spearman rank order correlation coefficient (r_s) and 95% confidence intervals (CI). R_s is interpreted in general guidelines by Colton (Colton, 1988) who suggested that values from 0.00 to 0.25 indicated little or no relationship; those from 0.25 to 0.50 suggest a fair degree of relationship; values of 0.50 to 0.75 are moderate to good; and values above 0.75 are considered good to excellent. Comparisons between the two IPM; speckle tracking of the ARA and segmentation of the urethra; were evaluated by Pearson's correlation coefficient after testing whether the values came from a Gaussian distribution (Kolmogorov–Smirnov test).

11.4 Results:

Correlation of urethral displacements and ARA displacement to the two validated digital examination scoring systems will be presented first on all participants and then subsets of normal and SUI groups.

Once the validity of the IPM is established, correlation of the same IPM to the novel Functional Scale described in Chapter 9 will be reported, first on all participants and then subsets of normal and SUI groups.

Finally, the correlation between the two different IPM and PF structures, speckle tracking of the ARA and segmentation of the urethra, during a PFM contraction will be described on subsets of normal and SUI groups.

11.4.1 Correlation between urethral displacements measured by segmentation and digital palpation scales:

11.4.1.1 Ventral displacement of the urethral edge: There was a statistically significant fair to good correlation (r_s = 0.46 to 0.65) between the ventral displacement of both edges of the urethra measured by segmentation IPM and all digital palpation scales (Table 11.1).

Table 11.1: Correlation of the ventral (X) displacement of the urethral edge measured by segmentation to validated PFM palpation scales; n = 32.

	Anterior Edge			Posterior Edge		
Test	Oxford	Deep	Superficial	Oxford	Deep	Superficial
(r_s)	**0.58**	**0.54**	**0.56**	**0.68**	**0.63**	**0.70**
P	**0.0002**	**0.0008**	**0.0005**	**<0.0001**	**0.0003**	**<0.0001**
95% CI	0.28 to 0.78	0.22 to 0.75	0.25 to 0.76	0.42 to 0.83	0.36 to 0.81	0.45 to 0.84

There was a stronger association between the digital scales and displacement of the posterior edge compared to the anterior edge as indicated by the higher correlation coefficient and the narrower CI. The narrow CI obtained from the correlation between digital palpation and ventral displacement of the posterior edge of the urethra suggests that given a worst case scenario, there would be a fair correlation, and given the best case, an excellent correlation.

Once the investigation is separated into subgroups, the analysis reveals that in the SUI group there is a statistically significant good to excellent correlation between ventral displacement of both edges of the urethra and all digital scales (r_s = 0.70 to 0.83), except between the anterior urethral edge and the Superficial scale which is moderate (r_s = 0.57) and not quite significant (P = 0.06). In the continent group both urethral edge displacements have a statistically significant fair to good correlation with all digital scales (r_s = 0.39 to 0.65).

11.4.1.2 Cranial Displacement of the urethral edge: There was a statistically significant fair correlation (r_s = 0.32 to 0.45) between the cranial displacement of both edges of the urethra measured by segmentation IPM and all digital scales (Table 11.2). There was a slightly higher correlation coefficient and narrower CI between the posterior edge and digital scales than the anterior edge and digital scales; however the CI's were all wider than in a ventral direction.

Table 11.2: Correlation of the cranial (Y) displacement of the urethral edge measured by segmentation to validated PFM palpation scales; n = 32.

	Anterior Edge			**Posterior Edge**		
Test	Oxford	Deep	Superficial	Oxford	Deep	Superficial
(r_s)	**0.35**	**0.36**	**0.32**	**0.45**	**0.43**	**0.42**
P	**0.025**	**0.021**	**0.038**	**0.006**	**0.009**	**0.011**
95% CI	-0.01 to 0.63	0.01 to 0.64	-0.05 to 0.61	0.01 to 0.70	0.07 to 0.69	0.06 to 0.68

Separating the analysis down in SUI and continent groups reveals that in the SUI group there is a statistically significant correlation between the cranial displacement of the posterior edge of the urethra and all digital scales (r_s = 0.67 to 0.74). The continent group only reaches significance when cranial posterior urethral displacement is compared to the Oxford scale (P = 0.045, r_s = 0.38), although the Deep and Superficial scales indicate a strong trend (P = 0.06, r_s = 0.34 to 0.35). There is no statistically significant correlation between cranial displacement of the anterior edge and any digital scale in the continent group (r_s = 0.26 to 0.33), whereas the SUI group reaches statistical significance in both the Oxford and Deep scales (r_s = 0.67 and 0.63) respectively and shows a strong trend in the Superficial scale (P = 0.06, r_s = 0.56).

11.4.1.3 Overall resultant displacement of the urethral edge:

There was a statistically significant fair correlation (r_s = 0.42 to 0.50) between the resultant displacement of the urethra measured by segmentation IPM and all digital scales (Table 11.3). Once again, the posterior edge displacement indicated a higher correlation to the digital scales than the anterior edge.

Table 11.3: Correlation of the overall resultant (R) displacement of the urethral edge measured by segmentation to validated PFM palpation scales; n = 32.

	Anterior Edge			**Posterior Edge**		
Test	Oxford	Deep	Superficial	Oxford	Deep	Superficial
(r_s)	**0.46**	**0.47**	**0.42**	**0.50**	**0.50**	**0.48**
P	**0.004**	**0.003**	**0.008**	**0.002**	**0.002**	**0.003**
95% CI	0.12 to 0.70	0.13 to 0.71	0.07 to 0.68	0.16 to 0.73	0.16 to 0.73	0.14 to 0.72

Dividing the analysis into SUI and continent groups, the SUI indicated statistically significant good to excellent correlations between all digital scales and overall displacement of both edges of the urethra (r_s = 0.71 to 0.84). The continent group also reached statistical significance in all digital scales, although the correlations were more moderate (r_s = 0.39 to 0.52).

11.4.2 Correlation between ARA displacements measured by speckle tracking and digital palpation scales:

There was a statistically significant fair correlation (r_s = 0.30 to 0.49) between displacement of the ARA in all directions measured by speckle tracking and all digital palpation scales (Table 11.4). Once again, there is a trend that ventral displacement of the ARA has a stronger correlation, although the CI are wide and do overlap.

Table 11.4: Correlation of ARA displacement in a ventral, cranial and resultant direction to PFM palpation scales (SF = Superficial scale); n = 32.

	Ventral Displacement (X)			**Cranial Displacement (Y)**			**Overall Displacement (R)**		
Test	Oxford	Deep	SF	Oxford	Deep	SF	Oxford	Deep	SF
(r_s)	**0.45**	**0.39**	**0.49**	**0.29**	**0.36**	**0.31**	**0.39**	**0.41**	**0.43**
P	**0.004**	**0.012**	**0.002**	**0.050**	**0.019**	**0.037**	**0.012**	**0.010**	**0.007**
95% CI	0.12 to 0.70	0.05 to 0.65	0.16 to 0.72	-0.08 to 0.58	0.01 to 0.63	-0.04 to 0.60	0.04 to 0.65	0.06 to 0.66	0.08 to 0.68

Separate analysis of the continent and SUI groups indicates that in a ventral direction, the continent group has a statistically significant fair to moderate correlation (r_s = 0.39 to 0.51) to all digital scales whereas the SUI group shows a statistically insignificant poor to fair correlation (r_s = 0.18 to 0.42). In a cranial direction, neither group indicate a statistically significant correlation, with the continent group having coefficients of value (r_s = 0.21 to 0.34) and the SUI group (r_s = 0.01 to 0.52).

In the continent group, overall resultant displacement has a statistically significant correlation with the Superficial scale only (P = 0.02 r_s = 0.42). The Oxford and Deep scales indicate a non significant fair correlation (r_s = 0.28 to 0.29) respectively. The correlations in the SUI group between digital scales and overall resultant displacement are also not significant (r_s = 0.01 to 0.55), although the Deep scale indicates a trend towards significance (P= 0.066).

Summary: The results of the correlation analysis between the displacement values obtained with IPM and digital palpation indicate a fair to excellent association, and are at the very least, consistent with other validity testing of ultrasound measurements to digital examination. It seems reasonable to assess the validity of the Functional Scale by comparison of the results of the digital examination to the displacement values obtained from TP ultrasound combined with IPM.

11.4.3 Correlation between displacements measured with TP ultrasound combined with IPM and the Functional Scale:

11.4.3.1 Urethral displacement: The Functional scale has a highly statistically significant moderate to good correlation to the displacement of both edges of the urethra measured with TP ultrasound imaging combined with IPM in all directions (r_s = 0.48 to 0.65) (Table 11.5).

Table 11.5: Correlation of displacement of the urethra measured by IPM to the Functional Scale; n = 32.

Test	**Anterior Edge**			**Posterior Edge**		
	X	Y	R	X	Y	R
(r_s)	**0.65**	**0.48**	**0.55**	**0.65**	**0.55**	**0.54**
P	**<0.0001**	**0.0026**	**0.0005**	**<0.0001**	**0.0008**	**0.0011**
95% CI	0.38 to 0.82	0.15 to 0.72	0.05 to 0.68	0.36 to 0.82	0.23 to 0.76	0.21 to 0.76

The CI's in the ventral displacement of both edges are quite narrow, indicating at worst, a moderate correlation.

Analysis of the separate groups reveals that in the SUI group, there are statistically significant good to excellent correlations (r_s = 0.63 to 0.88) between urethral displacement measured with IPM and the Functional scale except between the cranial displacement of the anterior edge which is not significant (r_s = 0.53, P = 0.074). In the continent group, there are statistically significant fair to moderate correlations between the Functional scale and urethral displacements in all directions (r_s = 0.47 to 0.62).

11.4.3.2 ARA displacement: The Functional scale has a statistically significant moderate correlation to displacement of the ARA in all directions (r_s = 0.44 to 0.53) (Table 11.6). The CI's are generally wider than correlations between urethral displacement and the Functional scale.

Splitting the analysis into SUI and continent groups indicates that in the SUI group, there are statistically significant, good to almost excellent correlations between the Functional Scale and ARA displacement measured in all directions (r_s = 0.61 to 0.74). The continent group also indicates statistically significant but more moderate correlations between ARA displacement in all directions (r_s = 0.41 to 0.59).

Table 11.6: Correlation of displacement of the ARA measured by IPM to the Functional Scale; n = 32.

Test	**ARA Displacement**		
	X	**Y**	**R**
(r_s)	**0.54**	**0.44**	**0.51**
P	**0.0006**	**0.0048**	**0.0013**
95% CI	0.23 to 0.75	0.11 to 0.69	0.19 to 0.73

11.4.4 Correlation between the displacement of the ARA and the urethra measured by image processing methods:

The results were normally distributed in both groups. In the continent group there was highly statistically significant excellent correlation (P < 0.001 r_s = 0.74 to 0.87) between the amounts of displacement of the ARA to the displacement of both edges of the urethra during a maximum perceived voluntary PFM contraction in all directions (Table 11.7).

Table 11.7: Correlation of ARA displacement to Urethral displacement during a voluntary PFM contraction; n = 23 continent, n = 9 SUI.

	Test	**Continent** Edge of Urethra Anterior	 Posterior	**SUI** Edge of Urethra Anterior	 Posterior
ARA Displacement (X)	(r_s)	**0.79 P<0.0001**	**0.81 P<0.0001**	**0.71 P = 0.03**	0.61 P=0.08
	95% C.I.	0.54 to 0.91	0.58 to 0.92	0.09 to 0.93	-0.09 to 0.91
ARA Displacement (Y)	(r_s)	**0.74 P<0.0001**	**0.79 P<0.0001**	0.57 P=0.11	0.66 P=0.06
	95% C.I.	0.45 to 0.89	0.54 to 0.91	-0.15 to 0.90	-0.02 to 0.92
ARA Displacement (R)	(r_s)	**0.87 P<0.0001**	**0.87 P<0.0001**	**0.67 P = 0.05**	0.56 P=0.11
	95% C.I.	0.70 to 0.95	0.71 to 0.95	0.02 to 0.92	-0.16 to 0.89

In the SUI group, the correlation coefficients are lower and only significant between the ARA and the anterior urethral edge, although there is at least a moderate to good relationship (r_s = 0.56 to 0.71).

11.5 Discussion

The significant correlation between the measurements of ARA and urethral displacement during a voluntary PFM contraction and PFM strength measured using validated manual muscle testing (Laycock & Jerwood, 2001;Devreese *et al.*, 2004) supports the use of these novel image processing methods and TP ultrasound analysis in the assessment of PFM function.

11.5.1 Correlation between Oxford scale and urethral displacement:

In this current study, the overall cranioventral displacement (R) and Oxford scale indicate correlation coefficients of r_s = 0.46 (anterior edge) and r_s = 0.50 (posterior edge). There are two other 2D TP studies which have compared the correlation between strength of PFM contraction measured by the modified Oxford scale and overall cranioventral displacement of the bladder neck (BN) measured using traditional ultrasound methods, (Chapter 2 Section 2. 11.2.2) (Dietz *et al.*, 2002;Thompson *et al.*, 2006b). It is unclear whether they took the midpoint or the anterior edge of the BN as a reference point, but both studies indicated a statistically significant correlation coefficient of between r = 0.52 and r_s= 0.58 respectively although Dietz et al used a Pearson

Correlation coefficient for analysis, instead of non-parametric analysis. The power of both these studies was much higher than this current study with subject numbers of 87 and 120 women respectively, which allows for greater confidence in the strength of association. However a more recent study of 209 women with various PFM dysfunctions, used 3D transvaginal ultrasound to measure the BN distance from the lower border of the SP during a voluntary PFM contraction and correlated the results to Oxford Scale digital examination (Yang *et al.*, 2009). They indicated a weak but significant correlation using a Pearson's correlation coefficient ($r = 0.19$, $P = 0.013$).

This current study was able to separately calculate the ventral and cranial displacements of the urethra. The ventral displacement (X) pushes the urethra towards the symphysis pubis (SP), describing the "squeeze" felt on vaginal palpation, and the cranial displacement (Y) describes the "lift". The higher correlation coefficients in the ventral direction ($r_s = 0.58$ to 0.68) compared to the cranial direction ($r_s = 0.35$ to 0.45) suggests that there is a stronger correlation between the ventral squeeze displacement and strength of PFM contraction than the lift.

In this current study, correlations were also calculated for the subgroups of continent and SUI women to establish whether the association was comparable in both subgroups. In all directions of urethral displacement, the correlations between Oxford scale and displacement are higher in the SUI ($r_s = 0.74$ to 0.82) than continent group ($r_s =$ 0.38 to 0.42) which is in agreement with the study reported by Thompson et al (Thompson *et al.*, 2005).

11.5.2 Correlation between Oxford Scale and ARA displacement:

No 2D TP ultrasound study to date has examined the association of movement of the ARA to vaginal palpation scores, although the transvaginal ultrasound study reported by Yang et al (Yang *et al.*, 2009) measured shortened sagittal hiatal diameters, measured from the SP to the ARA. They measured the distance from the SP to the ARA, which reduces as the PFM contracts, therefore they reported a negative, statistically significant fair correlation with PFM contraction ($r = -0.348$, $P < 0.001$). A fair, significant negative correlation ($r = -0.32$, $P = 0.024$) between Oxford grading during PFM contraction to reduction in hiatal dimensions was also found in an observational study using 3/4D ultrasound in 55 women of undetermined continence status (Dietz *et al.*, 2006). Both studies used the parametric Pearson's correlation coefficient for statistical analysis. In this current study, the measurements are taken from the ARA to the SP therefore the distance increases and there will be a positive correlation. The change in hiatal diameter is equivalent to the overall resultant displacement (R), which indicated a fair positive correlation ($r_s = 0.39$, $P = 0.012$). In this current study, breaking the analysis ventral "squeeze" and cranial "lift" components of PFM contraction, the ventral displacement of the ARA indicated a stronger correlation than the cranial or resultant displacement (R), which is a similar trend to the correlations between urethral displacement and Oxford Scale.

The statistically significant correlations between strength of PFM contraction and overall displacement of the urethra or ARA found in this current study using TP ultrasound and IPM, and the studies previously reported (Dietz *et al.*, 2002;Thompson *et al.*, 2005;Thompson *et al.*, 2006b;Dietz *et al.*, 2006;Yang *et al.*, 2009) support the validity of urethral or ARA displacement to measure PFM contraction. However these fair to moderate correlations suggest that the overall amount of displacement of the pelvic organs during a voluntary PFM contraction is dependent on a variety of factors other than the force of the PFM contraction. As discussed earlier, the amount of displacement could be substantial, not because the muscle is strong, but the potential range of motion is greater. As observed in Chapter 6, the starting position of the ARA and urethra varies between individuals and between groups. The ARA and urethra is lower and more dorsally placed in the SUI compared to the continent group, so even if the PFM muscles are weak, they may be able to displace the PF or bladder as much as a women who has a very strong PFM, but little available range. However, this current study was able to measure the separate components of urethral and ARA ultrasound displacement, and indicated better correlations with ventral displacement across both groups, perhaps suggesting that the "squeeze" component is less affected by anatomical and physiological variations than the "lift".

11.5.3 Correlation between Deep and Superficial scales and pelvic organ displacement:

This is the first study to examine the correlation between the displacement of the ARA and urethra during a PFM contraction and a scoring system that attempts to distinguish between the deeper and more superficial aspects of the PF (Devreese *et al.*, 2004). There were statistically significant, fair to moderate correlations with urethral and

ARA displacements in all directions. It may have been expected that the Deep scale, where the palpating finger position is deep within the vagina, may have had a stronger correlation to ARA displacement, and similarly the Superficial scale, where the contraction is felt closer to the introitus, would have a better correlation with the urethral displacement, however this was not indicated and the correlations were very similar to the results obtained with the Oxford scale.

11.5.4 Validity of the Functional scale:

In support of the validity of the Functional Scale, this study suggests that in both continent and SUI women, there is a statistically significant, fair to excellent correlation to the amount of displacement of both the ARA and urethra in all directions (r_s = 0.41 to 0.88). Perhaps unsurprisingly, the Functional scale, which measures displacement rather than strength of PFM contraction, has a stronger correlation to displacement of the urethra and ARA than the other digital scoring systems. The Functional Scale seems able to more easily accommodate differences in individual anatomy and physiology as in order for the contraction to score highly, the voluntary PFM contraction needs to be able to elevate and compress the urethra, wherever it is positioned anatomically, and however the muscles of the lumbo-pelvic cylinder interact.

Like the other digital scales of measurement, the Functional Scale seems particularly to measure the squeeze component of the voluntary PFM contraction. This is indicated by the consistently stronger correlation with the ventral displacement of both the ARA and urethra compared to the cranial displacement, particularly in the SUI group. However in the SUI group, the cranial displacement of the anterior edge of the urethra did not reach significance, although the posterior edge did. One reason that the cranial displacement was different between urethral edges in the SUI group could be attributed to a potential confounder observed in some, but not all of the women with SUI. In these women, during a PFM contraction, the anterior edge appeared to shift cranially, independently of the posterior edge. The movement could be attributed to fascial damage, contraction of smooth and striated muscles within the urethral wall, or the superficial muscles of the urogenital diaphragm, but it is unclear why in some women this produced a significant cranial movement of the anterior edge without simultaneous movement of the posterior edge of the urethra. It is thought that an increase in increased intra-abdominal pressure can sometimes exert an opening shear force on the proximal urethra produced by unequal separation of the anterior and posterior urethral walls (Koelbl *et al.*, 2002). Perhaps this phenomenon is being described by segmentation IPM of the urethra, but further research is required to corroborate this occasional descriptive finding. Irrespective of this potential confounder, measurement of the cranial component still shows good correlation with palpation using the Functional Scale.

Although the association between the Functional Scale and displacement was comparable in both subgroups of women, the SUI group indicated slightly higher, if not always statistically significant correlations (SUI r_s = 0.53 to 0.88; continent r_s = 0.47 to 0.62). As in the other digital scales, the higher value of r_s but comparable or lower P values in the SUI compared to the continent group is indicative of the smaller number in this group, but may also reflect the greater variability of scores within the SUI group. For example, in the continent group, almost 75% scored 4 on the Functional palpation score.

11.5.5 Correlation between displacement of the ARA and urethra:

This is the first study to correlate the movement of the ARA to movement of the urethra during a PFM contraction. Two different IPM were used in this current study; segmentation was used to measure the urethral displacement and speckle tracking was used to ARA displacement. In the continent group, there were excellent, highly significant correlations between the displacement of the ARA and displacement of the urethra in all directions ($P < 0.001$; r_s = 0.74 to 0.87), whereas in the SUI group, there were moderate to good correlations (r_s = 0.56 to 0.71) which were not always significant. This may be due, in some part, to the small sample size in the SUI group, however may also be reflective of more intact anatomy of the continent group. As discussed earlier, the pubovisceralis wraps around the ano-rectal junction and attaches to the SP, so that a PFM contraction makes the ARA more acute and should displace the urethra in a cranioventral direction(Constantinou *et al.*, 2002)Should the pubovisceralis not be intact, or the urethra or bladder be prolapsed, which is more likely in the SUI group, a voluntary PFM is less likely to displace the BN. Theoretically there could be large ARA displacements without concurrent urethral displacements. In the continent group, this study indicates that there is an excellent correlation between larger displacements of the ARA with larger displacements of the urethra, conversely, smaller displacements of the ARA producing smaller urethral displacements. In the SUI group, the ARA correlations are only significant between the overall resultant and ventral displacement of the anterior edge of the urethra. It therefore seems that the stronger correlations between digital strength of contraction and urethral displacements compared to digital strength of contraction and ARA displacement is more attributable to intact anatomy rather than the different qualities of the two different IPM.

11.5.6 General discussion:

Voluntary PFM contraction is thought to occur in three planes: cranial lift, transverse and sagittal squeezes (Sherburn *et al.*, 2005;Thompson *et al.*, 2005;Dietz *et al.*, 2002;Thompson *et al.*, 2007). This current study has validated digital strength with displacement of both the urethra and ARA in a sagittal direction, using components of overall displacement (R), or shortest distance, cranial (Y) lift and ventral (X) squeeze. Our current study indicates that for both continent and SUI women, ventral displacement or squeeze in a sagittal direction correlates better to digital strength than overall displacement or cranial lift. Medio-lateral or transverse squeeze is currently not accessible using 2D ultrasound and has been ignored in this current study, which may also account, in part, for the fair to moderate correlations with strength evaluated by digital assessment.

Our findings (r = 0.46 to 0.50) are in general agreement with those TP 2D and 3D/4D ultrasound studies indicating a fair to good correlation between overall BN displacement and digital evaluation of PFM strength(Dietz *et al.*, 2002;Thompson *et al.*, 2005;Thompson *et al.*, 2006b). However, they are not in agreement with displacement measured using TV ultrasound (Yang *et al.*, 2009) or one study using TA ultrasound (Sherburn *et al.*, 2005) in which both indicated poor association with digital strength (r = 0.19 and 0.21) respectively. Some of the disagreement can be explained by the limitations of both TA and TV ultrasound. As discussed earlier (Chapter 2, Section 2.12.2) measurements taken of the BB during TA ultrasound do not have a reference point in which to consistently measure from, so divergent measures, that is depression of the BN on TP ultrasound can occur with elevation of the BB on TA ultrasound, and visa versa (Thompson *et al.*, 2005). Any intravaginal device, however carefully placed may artificially displace the PF structures and will increase the stiffness of the PF structures, so perhaps affecting the displacement values recorded. However, neither explanation alone can account for the differences observed, particularly as one other TA study has indicated fair correlation between displacement of the BB and digital examination (r = 0.46) (Thompson *et al.*, 2005). Therefore the differences most likely reflect different methodologies, particularly the measurement methods, or the study populations, as well as the confounders associated with how much available range there may be due to fascial laxity, and starting position of the pelvic structures.

Until recently, 2D ultrasound studies have focused upon the cranioventral displacement of the BN or BB during a PFM contraction which also relies upon intact myofascial attachments of the PFM and urethra, without significant prolapse of the bladder, or restricted BN motion by pelvic surgery (Yang *et al.*, 2009) This current study, the overall displacement (R) between the SP and ARA (r = 0.39) is in close agreement with both the 2D TV and 3D/4D ultrasound studies measuring the hiatal diameter, or the sagittal distance from ARA to SP during a PFM contraction which indicated a fair correlation to digital strength (r = -0.32 to -0.35) (Dietz *et al.*, 2006;Yang *et al.*, 2009). Furthermore, this current study was able to determine that the sagittal displacement in a ventral (X) direction (or squeeze) has better correlation to digital strength than the cranial lift or overall displacement. However, the correlation is still only fair to moderate (r = 0.45) which suggests, due to the confounders discussed earlier and the inability of 2D to measure medio-lateral or transverse squeeze, there is neither published nor clinical evidence which suggests that there is a single tool available to fully assess PFM action (Yang *et al.*, 2009). In the future, 3D/4D ultrasound may allow clarification of the change in transverse squeeze, however to date; shortened transverse diameter at rest and during a PFM contraction using 3D/4D ultrasound has been shown to be an unreliable measurement (Braekken *et al.*, 2008;Braekken *et al.*, 2009).

This current study was also able to correlate displacement of the ARA and urethra during a PFM contraction, using two different IPM. A greater displacement of the ARA implies greater displacement of the urethra in continent women as indicated by the highly statistically significant excellent correlations. However in women with SUI, the more moderate and occasionally insignificant correlations between ARA and urethral displacements emphasises that the lack of displacement of the urethra, does not necessarily imply lack of movement of the ARA or visa versa.

In order to try and account for individual anatomy, and the confounders associated with fascial laxity, resting PFM tone, as well as the levels of intra-abdominal pressure and activity of the other muscles of the abdominal-pelvic cavity, a simple digital scale to measure a function of the PFM, particularly relevant for women with SUI, was proposed by the author. The Functional Scale was shown to be a valid PFM measure and indicated statistically significant moderate to excellent correlation with both urethral and ARA displacement in all directions, but particularly the ventral squeeze component. As discussed earlier (Chapter 9, Section 9.5.2) matters of test-retest reliability, responsiveness and sensitivity to change which would need to be addressed in a future study before the absolute usefulness of the Functional scale could be determined.

11.6 Conclusions:

TP ultrasound combined with IPM is a valid measure of PFM function and the correlations between digital examination and ultrasound measurements were comparable for subgroups of continent and SUI women. However, other than the Functional scale, which does not measure strength, the correlations with digital palpation scales were moderate suggesting that greater displacement of the PF is not an extremely sensitive measure of PFM strength. Displacement of the ARA correlates highly with displacement of the urethra in continent but more moderately in women with SUI. The Functional Scale is a valid digital measurement of PFM displacement which has good correlation with TP ultrasound and IPM which appears to account for differences in individual anatomy and muscle function.

As discussed earlier, currently there is not one single measurement tool available to fully assess PFM action. The following chapter describes the preliminary investigation of a novel vaginal pressure probe designed to enable the specific localisation and measurement of the pressure changes in a medio-lateral as well anterio-posterior direction that occur in the vagina during a PFM contraction.

12 Vaginal Pressure Profile at Rest and During a Voluntary Pelvic Floor Muscle Contraction.

12.1 Introduction:

In order to measure PFM strength and endurance, various trans-vaginal devices including the dynamometer, instrumented speculum, perfusion profilometer and the directional probe have developed (Guaderrama *et al.*, 2005b;Dumoulin *et al.*, 2003;Morgan *et al.*, 2005;Constantinou & Omata, 2007). The dynamometer (Dumoulin *et al.*, 2003) and instrumented speculum (Morgan *et al.*, 2005) provide data specifying the resting and maximal closure force along the entire vagina but cannot detect the local area upon which pressures are imposed by the PFM contraction. The profilometer (Guaderrama *et al.*, 2005b) enabled the evaluation and localization of the closure pressures imposed upon the vaginal walls at rest and by voluntary PFM contractions, however due to the nature of hydrostatic pressure measurements, it was unable to distinguish the closure pressures from different directions around the vaginal wall.

Quantitative measurement and spatial localization of the PFM are of clinical value in understanding the relationship of PFM to the urethra and their contribution to the continence (Baessler *et al.*, 2005; Devreese *et al.*, 2004). In addition, there is evidence to suggest that the superficial and deeper aspects of the PFM may need to be assessed separately (Devreese *et al.*, 2004) as well as the balance between right and left sides (Laycock and Jerwood, 2001).

This chapter describes a pilot study designed to measure the pressure profile of the vagina at rest and during PFM contractions using the novel directional probe (Constantinou & Omata, 2007) described in Section 3.5.2.

12.2 Aim

To determine the feasibility of a novel vaginal pressure probe to quantify the magnitude and spatial distribution of pressures acting around the vaginal walls at rest and during a PFM contraction.

12.3 Methods

Twenty six continent and ten stress urinary continent (SUI) women were evaluated. In order to standardise bladder volumes, volunteers were asked to void 1 hour before testing, then drink 450 ml of water and to refrain from voiding until after the test sequences.

In a supine, crook lying position with a pillow under the head and legs supported, the examiner (RLJ) digitally verified the ability of the volunteer to perform a sustained PFM contraction. Instructions to the volunteer to elicit a PFM contraction followed International Continence Society (ICS) guidelines "squeeze the muscles of the pelvic floor as if attempting to stop the flow of urine or prevent wind or flatulus escaping" with the addition of "squeeze around the back passage, as if you were trying to prevent breaking wind (flatus); bring that feeling forward towards the urethra/pubic bone and then lift, as if you were elevating the PFM, whilst breathing normally".

The force sensors and probe were then covered with a female condom turned inside out for extra lubrication and closed until they were inserted into the vagina. The diameter adjustor was gradually released until the sensors made contact with the vaginal wall. Contact of each sensor to the vaginal wall was confirmed through the real-time display of the signal on a laptop. Then, the probe was manually pulled-through the vagina at an approximate speed of 2cm/second whilst simultaneously recording the position of the probe and the pressures in four directions.

Three measurements were performed both at rest and during a PFM contraction for each subject. In order to prevent the inevitable fatigue of maintaining a PFM maximum contraction during withdrawal of the probe, subjects were advised to moderate contraction intensity to approximately half strength with a 10 second rest between contractions.

Errors in VPP measurements could be caused by the operator shifting or rotating the probe as the probe is pulled through the vagina. In order to verify the trajectory of the probe during the measurement and to determine the position of the probe relative to the pelvic floor structures around the vagina; the positional sensor or Flock of Birds (FOB) (Section 3.5.1) was attached to the handle of the vaginal probe. To visualize the location of the probe, transperineal (TP) ultrasound imaging was used as described in

Section 3.5, orientating the probe to image the bladder, urethra, urethro-vesical junction (UVJ) vagina, ano-rectal junction and symphysis pubis (SP) (Figure 12.1).

Values of the resting VPP, in terms of distribution along the vagina, and relative changes produced during a PFM contraction were visualized graphically. The impact of sustained PFM contraction on the VPP was calculated and the differences between continent and incontinent subjects evaluated. Algorithms used to evaluate the changes in pressure are given in Appendix 5c. Mean and Standard Error (SE) of the pressures were calculated and presented graphically. Statistical comparisons using two-tailed multiple Student's t-test with Bonferroni correction and one-way analysis of variation (ANOVA) were used. SPSS software windows version 14.0 (SPSS INC, IL) was used to perform these analyses. A 95% confidence interval ($P<0.05$) was used as the level of significance.

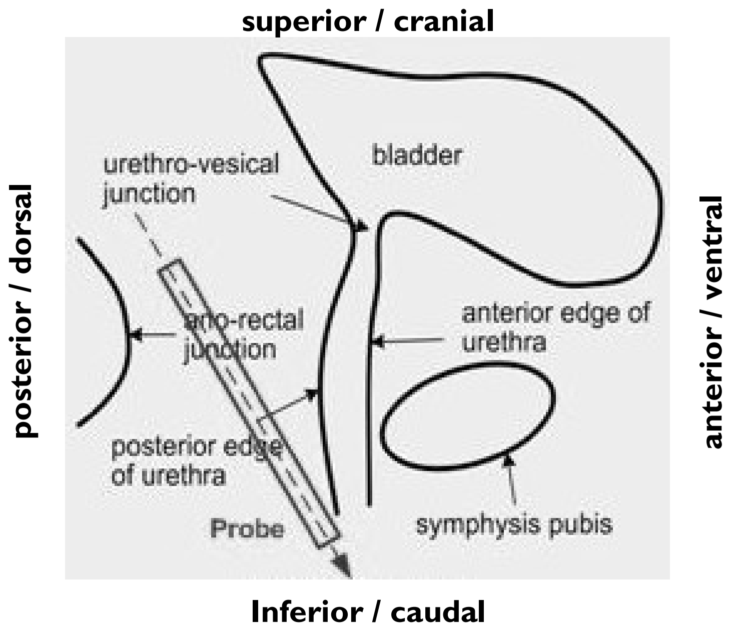


Figure 12.1: A schematic image of the probe and pelvic floor structures. The probe was manually withdrawn along the gray dashed arrow.

12.4 Results:

Three subjects were excluded from the analysis because of the recording failure of the vaginal probe in some direction(s). There was a significant difference between age of the 23 asymptomatic and 10 women with SUI women: mean and Standard Error (SE) was 39.0±2.3 years (parity 1) 51.5±5.3 years (parity 1). Between groups there was no significant difference in body mass index (BMI) continent = 22.4 +/-2.0, SUI 25.0+/-4.1. Determined by a severity scale (Sandvik *et al.*, 2000), 6 of the incontinent group were considered to be slightly incontinent; which equates to a few drops of urine a maximum of a few times a month; and 4 were considered to be moderately incontinent, a few drops or splashes of urine a maximum of a few times a week.

12.4.1 Position and trajectory of the vaginal probe:

Although Figure 12.1 shows schematically the vaginal probe being pulled-through along a straight trajectory vaginal pressure profile (VPP) measurement, the shape of the vagina is not straight so the insertion of the probe will deform the vaginal wall (Figure 12.2a,12.2b). The position of the probe relative to the pelvic floor structures around the vagina and the trajectory of the probe during VPP measurement were therefore evaluated using the FOB.

The sensor was pulled-though the vagina 8.3±0.8cm and the length between sensors and the bottom of probe was 8.0cm. Relative to the probe trajectory, estimated locations of the edge of SP and the UVJ were identified using ultrasound images (Figure 12.2c). The edge of SP and UVJ were 2.0±0.3 cm in the anterior direction and 4.3±0.1cm proximal from the introitus of the vagina, respectively.

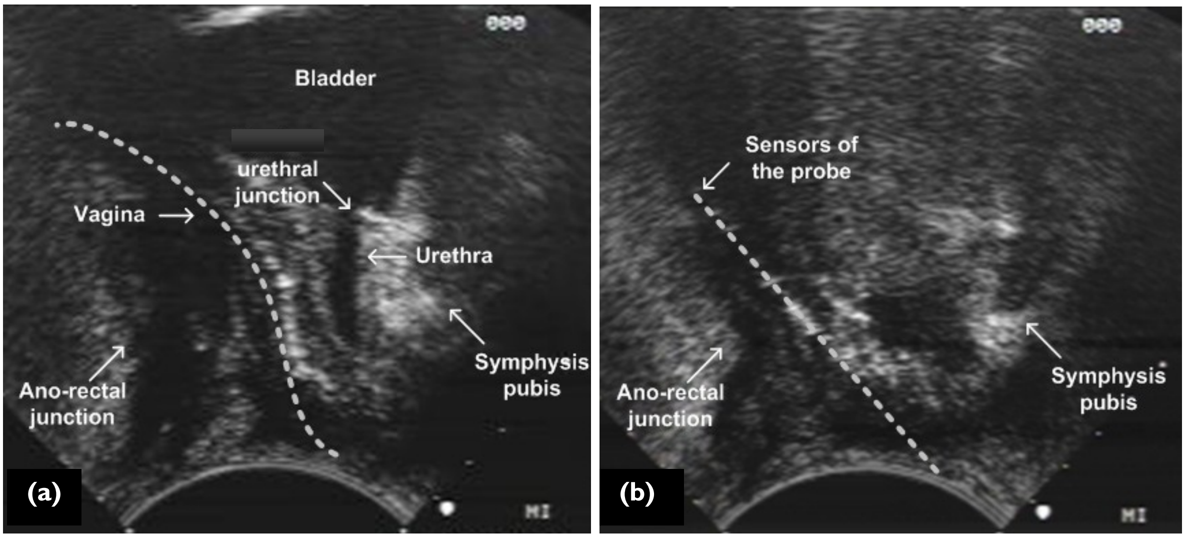
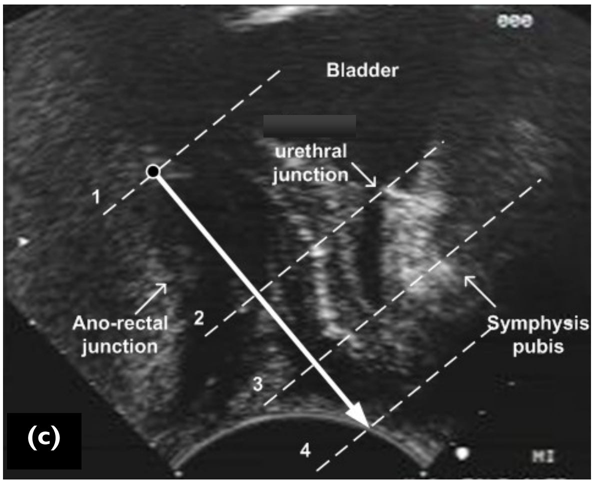
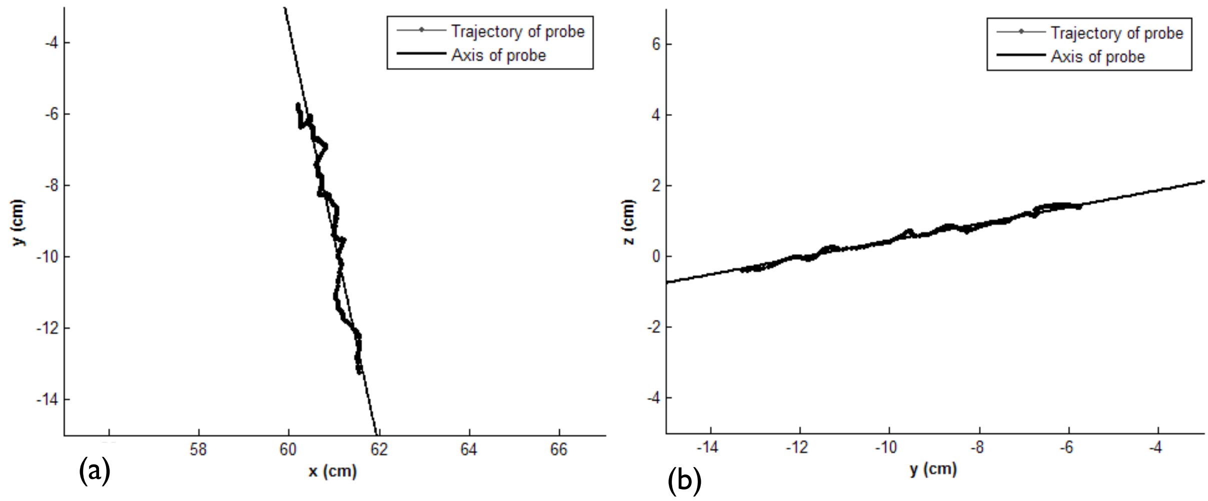


Figure 12.2: (a) Typical image frame of trans-perineal ultrasound without the probe. Gray dashed line: tracing of the shape of vagina. (b) A typical image frame of TP ultrasound with the probe. Gray dashed line: tracing of the shape of vagina with the probe.



(c) Vertical lines (white dashed) to the trajectory of sensor (white arrow). 1: vertical line at the start point (white circle) of trajectory. 2: vertical line at the UVJ. 3: vertical line at the edge of SP. 4: vertical line at the end point of trajectory (the introitus of vagina).

the probe (a straight line) and the relative roll angle of the probe was negligible (Figure 12.3). The maximum shift between the trajectory of with-drawing the probe and the axis of the probe was 0.3 ± 0.2cm; the maximum azimuth, elevation and roll angles were 3.0±1.5°, 2.0±0.6° and 2.9±1.5°, respectively.



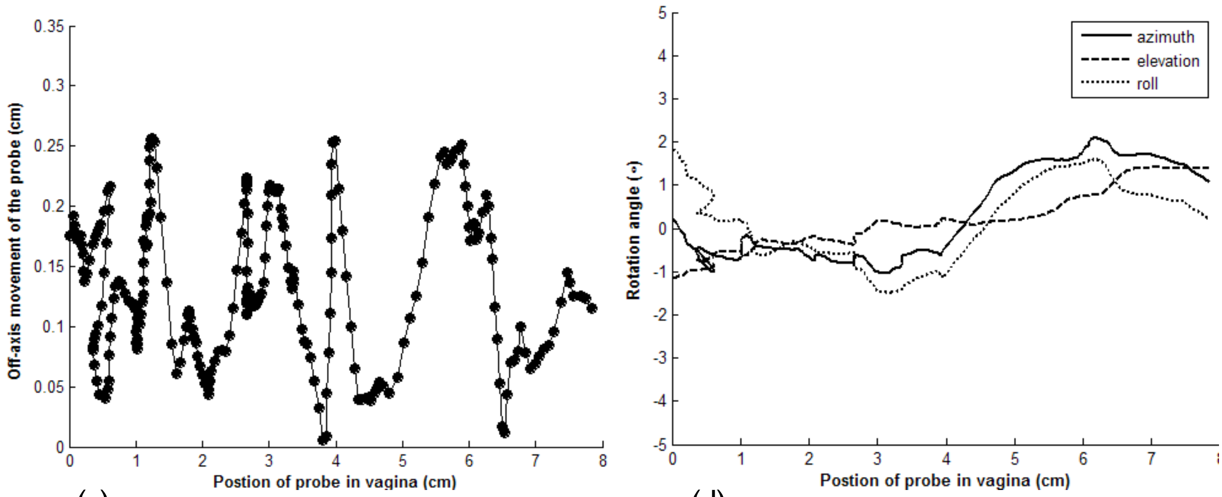


Figure 12.3: A typical record of trajectory of movement (dotted curve) and the axis of the probe (solid straight line) during the valid measurement. The movement and axis are projected to x-y plane and y-z plane in (a) and (b) respectively. (c) The distance between 3-D (x, y, z) trajectory of movement and axis of the probe. (d) The relative rotation angles of the probe.

12.4.2 Vaginal Pressure Profile

All profiles in each direction were aligned to the zero reference point (the entrance or introitus of the vagina) and then averaged to create the composite VPP profile. In each group, pressure values on the anterior and posterior vaginal wall were greater than those on the left and right sides (Figure 12.4) The profile curves on the anterior and posterior sides of the vaginal walls were different in shape (Figure 12.4a) whereas those shapes in the left and right sides were similar and balanced (Figure 12.4b).

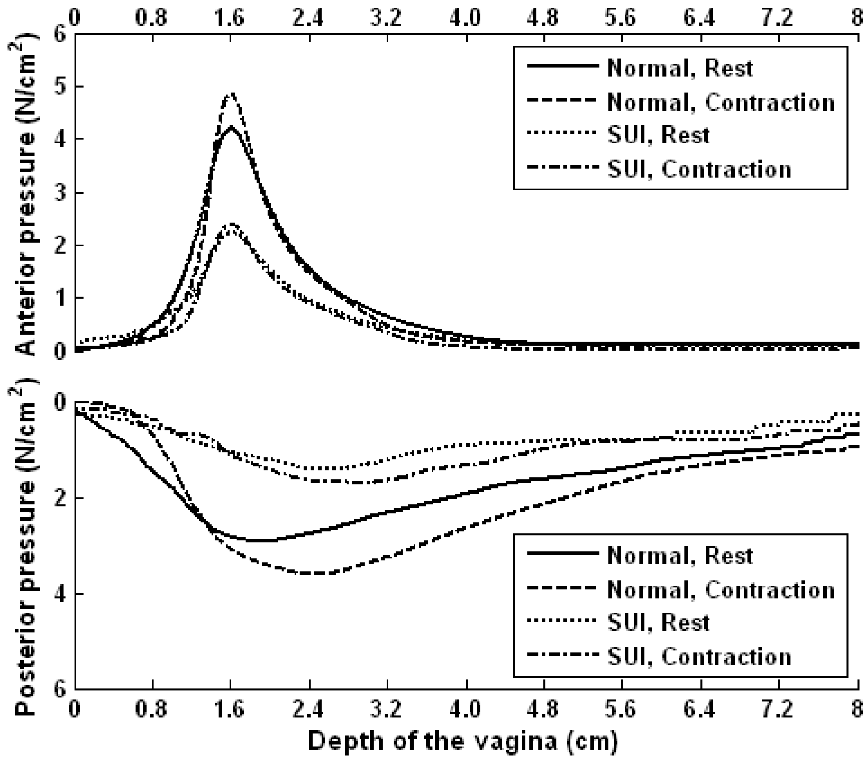
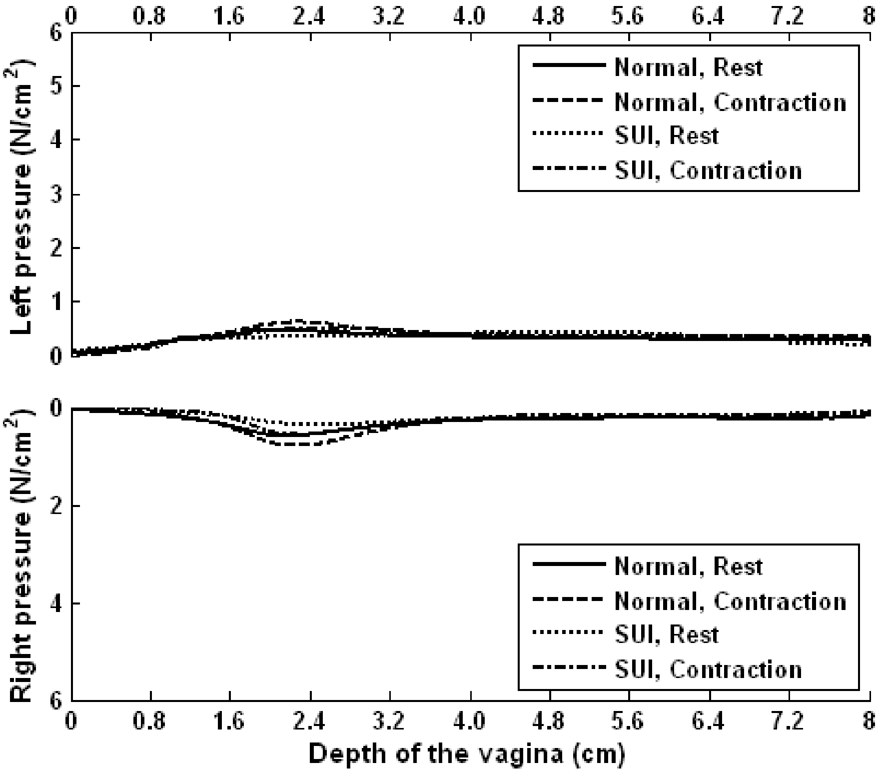


Figure 12.4a: Composite pressure profile in the anterior and posterior



Anterior Vaginal Pressure: At rest, the maximum anterior pressures were

Figure 12.4b: Composite pressure profile in the left and right directions.

1.5±0.1cm and SUI groups at 1.7±0.1cm proximal to the introitus of the vagina. In each group, this position was not changed significantly by a PFM contraction. The increases of pressure during a PFM contraction in continent and SUI group were only seen in a narrow segment with range of 1.4 to 2.0cm from the introitus of vagina (Figure 12.5). The averaged anterior pressures at rest and during PFM contraction are shown in Table 12.1. During a PFM contraction, the anterior vaginal pressure was significantly smaller than in the continent group.

Table 12.1: Maximum anterior pressure values at rest and during PFM contraction in continent and SUI group women (N/cm^2 ± Standard Error (SE)).
*: p<0.05, **: p<0.01, N.S.: no significance.

group	*Continent (n=23)*		*SUI (n=10)*
rest (N/cm^2)	3.8±0.5	—— N.S. ——	2.3±0.4
	| ** |		| N.S. |
PFM contraction (N/cm^2)	4.8±0.5	—— * ——	2.6±0.4

Posterior Vaginal Pressure: At rest, the maximum posterior pressures were recorded 0.4±0.2cm (continent) and 0.3±0.3cm (SUI) proximal from the point of the maximum anterior pressure of the vagina (p = 0.053). When the PFM contracted, there was an increase of pressure over a wider range compared to the anterior direction (Figure 12.5). The averaged positions of the maximum posterior pressures in continent females and SUI patients were 0.6±0.2cm and 1.2±0.2cm proximal from the peak point of anterior pressure (p=0.16), which is about 2.8 cm and 3.2 cm from the entrance of the vagina respectively. The averaged posterior pressures at rest and during PFM contraction are given (Table 12.2).

Table 12.2: Maximum posterior pressure values at rest and during PFM contraction in continent and SUI women (N/cm^2 ± Standard Error (SE)).
*: p<0.05, **: p<0.01, N.S.: no significance.

group	*Continent (n=23)*		*SUI (n=10)*
rest (N/cm^2)	3.4±0.3	—— * ——	2.0±0.4
	| ** |		| N.S. |
PFM contraction (N/cm^2)	4.2±0.3	—— ** ——	2.6±0.4

At rest and during a PFM contraction, the maximum posterior vaginal pressure of SUI patients was significantly lower than that of continent subjects. In addition, the continent group also had significant higher mean posterior VPP both at rest (continent: 1.67±0.13N/cm^2, SUI: 1.15±0.18N/cm^2, p=0.047) and with PFM contraction (continent: 2.05±0.13N/cm^2, SUI: 1.35±0.20N/cm^2, p=0.009).

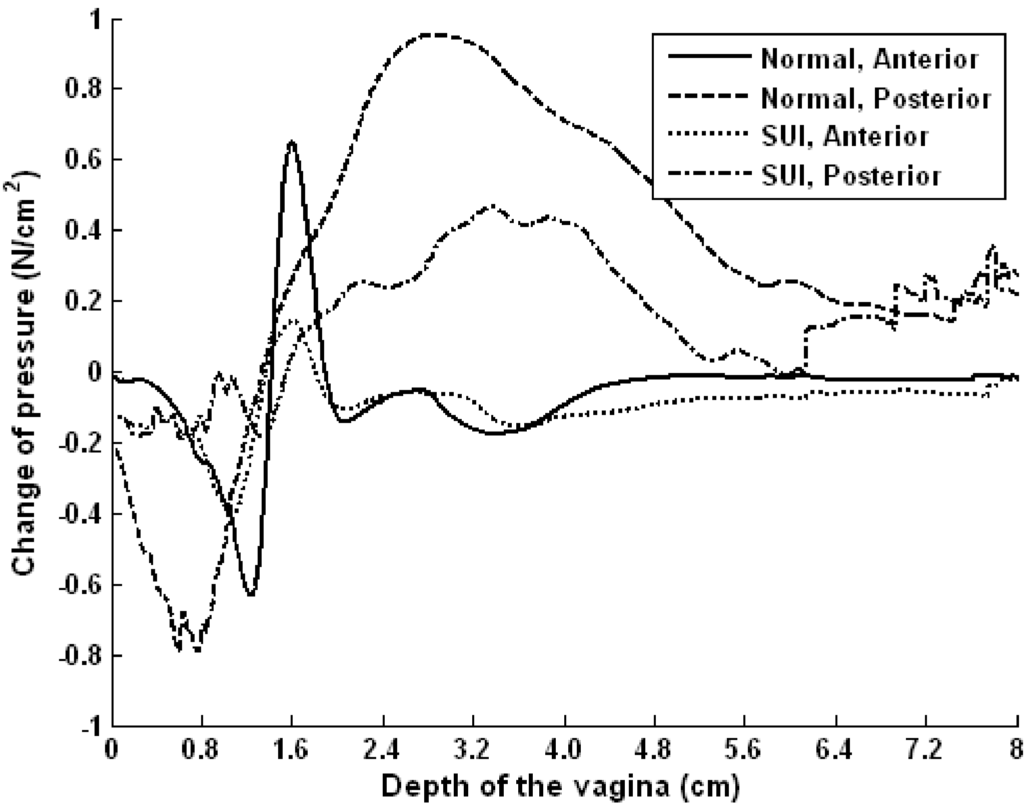


Figure 12.5: The change in anterior and posterior vaginal pressure profile (VPP) during a voluntary PFM contraction in continent and SUI women.

Lateral Vaginal Pressure: In both groups, at rest and during PFM contraction, the maximum lateral pressures were significantly less than the posterior or anterior pressures (Table 12.3) and they occurred within a similar position within the vagina, approximately 2.3cm from the introitus (Figure 12.6). Between groups, there were no significant differences between left and right vaginal pressures at rest or during a PFM contraction, although in the continent group, there was a significant change in pressure on the right side during a PFM contraction.

Table 12.3: Maximum lateral (left and right) pressure values at rest and during PFM contraction in continent and SUI women (N/cm^2 ± Standard Error (SE)).
*: p<0.05, **: p<0.01, N.S.: no significance.

Left direction	*group*	*Continent(n=23)*		*SUI (n=10)*
	rest (N/cm^2)	0.4±0.1	—— N.S. ——	0.4±0.1
		| N.S. |		| N.S. |
	PFM contraction (N/cm^2)	0.6±0.1	—— N.S. ——	0.6±0.1

Right direction

	rest (N/cm^2)	0.6±0.1	—— N.S. ——	0.5±0.04
		| * |		| N.S. |
	PFM contraction (N/cm^2)	0.9±0.1	—— N.S. ——	0.8±0.2

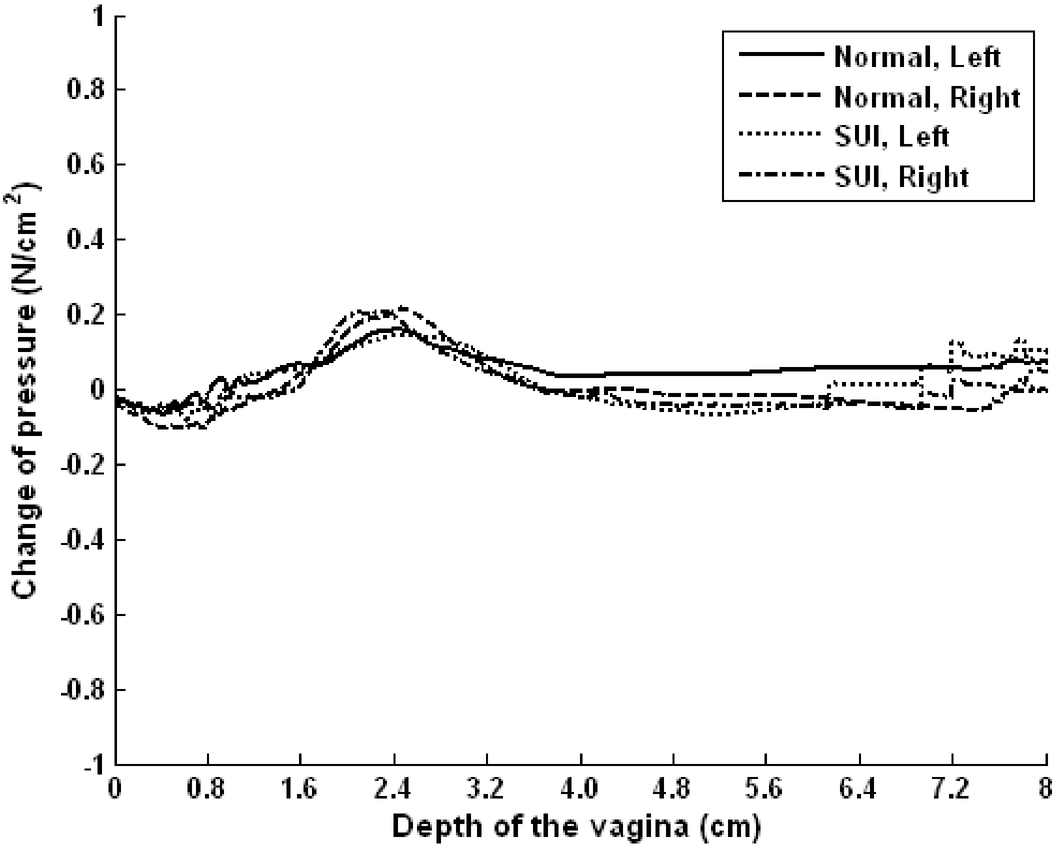


Figure 12.6: The change in lateral vaginal pressure profile (VPP) due to a voluntary PFM contraction in continent and SUI women.

12.4.3 True effect of a *PFM contraction on the VPP*

The recorded VPP pressures not only consist of the resting pressure but also the stretched passive pressure caused by the insertion of the vaginal probe. In order to obtain a true pressure reading caused by a voluntary PFM contraction these pressures must be subtracted from the total pressure caused by a PFM contraction (Detailed algorithms for calculations, Appendix 5C.2). After accounting for the presence of the probe and the resting pressure in the vagina; during a PFM contraction, the only significant difference in incremental pressure change between groups remained in the anterior direction (Table 12.4).

Table 12.4: Comparisons of the maximum values of the incremental change at rest and during PFM contraction in continent and SUI groups, once accounting for passive pressures (mean N/cm^2 ± Standard Error). *: $p<0.05$, N.S.: not significant.

	Anterior(N/cm^2)	*Posterior(N/cm^2)*	*Left(N/cm^2)*	*Right(N/cm^2)*
Continent (n=23)	1.42±0.22	1.98±0.21	0.34±0.05	0.47±0.08
	|	|	|	|
	*	N.S.	N.S.	N.S.
	|	|	|	|
SUI (n=10)	0.52±0.23	1.31±0.3	0.45±0.07	0.55±0.16

However, now the active pressure difference between the anterior and posterior walls of the vagina at rest and during a PFM contraction could be directly compared and located. In the continent group, there was a significant difference in the maximum pressures at rest and during PFM contraction, but not in the SUI group (Table 12.5, Figure 12.7). Comparing groups, both at rest and during a PFM contraction, continent women had a higher, statistically significant pressure difference.

Table 12.5: Comparisons of the maximum values of the active pressure differences between the posterior and anterior sides at rest and during PFM contraction in continent and SUI groups. (mean N/cm^2 ± Standard Error).
**: $p<0.01$ *: $p<0.05$, N.S.: not significant.

group	*Continent (n=23)*		*SUI (n=10)*
rest (N/cm^2)	2.45±0.26	—— * ——	1.35±0.27
	|		|
	**		N.S.
	|		|
PFM contraction (N/cm^2)	3.29±0.21	—— ** ——	1.85±0.38

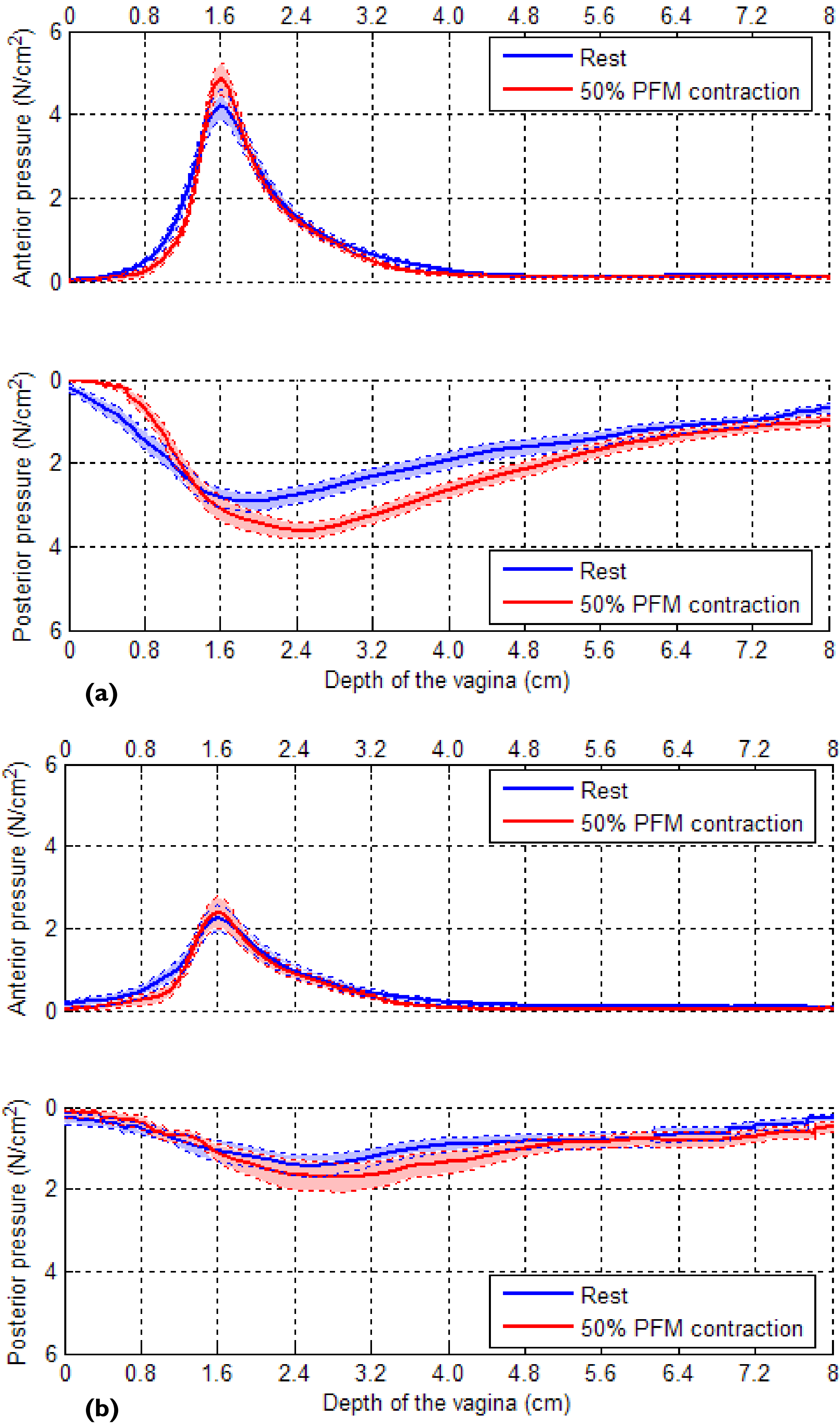


Figure 12.7: Direct VPP measurements in the Anterior/Posterior plane from: (a) continent; (b) SUI women. Blue and the red curves are average pressures at rest and during PFM contraction respectively. The standard errors are shown by the width of the shading.

3D representations of the distribution of the corrected pressures are given in Figures 12.8 and 12.9. The value of pressure is colour-coded to aid the anatomical visualization of the pressures by the probe, with blue representing the minimum value, and red the maximum. The maximum pressures in the continent group are at the 0, and 180 degree positions. Anteriorly at 0 degrees, the pressure is distributed quite narrowly, whereas posteriorly, there is greater spread. Figure 12.8b shows the 3-D distribution of the pressure of continent women during a 50% PFM contraction. A voluntary PFM contraction intensifies both the spread and degree of increased pressure. Adjusted pressures indicate that the maximum pressures are generated posteriorly, near the introitus (Figure 12.7c).

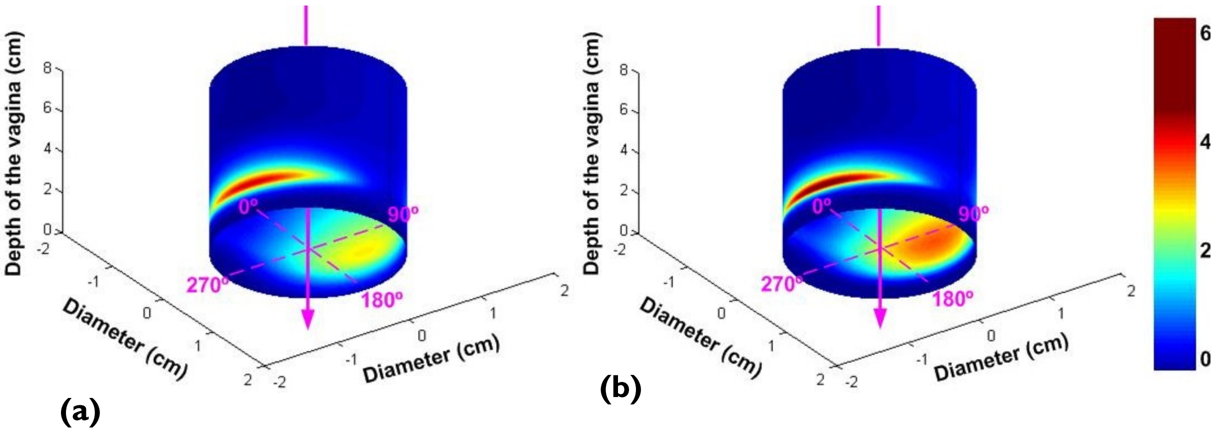


Figure 12.8: 3-D distribution of the pressures (a) at rest (b) during a 50% PFM contraction in continent women. N= 23.

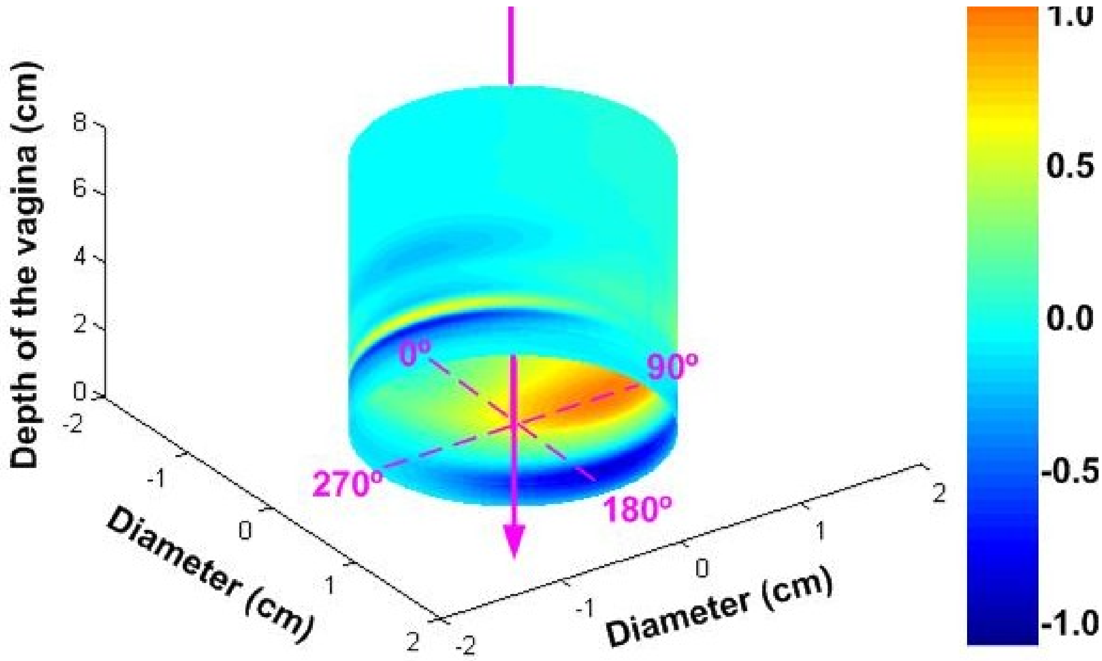


Figure 12.8c: Adjusted VPP between rest and 50% PFM contraction showing the 3-D distribution of the differences of the pressures in continent women. N= 23.

In SUI women, the 3D representation of pressures indicates a much lower intensity both at rest and also during a PFM contraction (Figure 12.9).

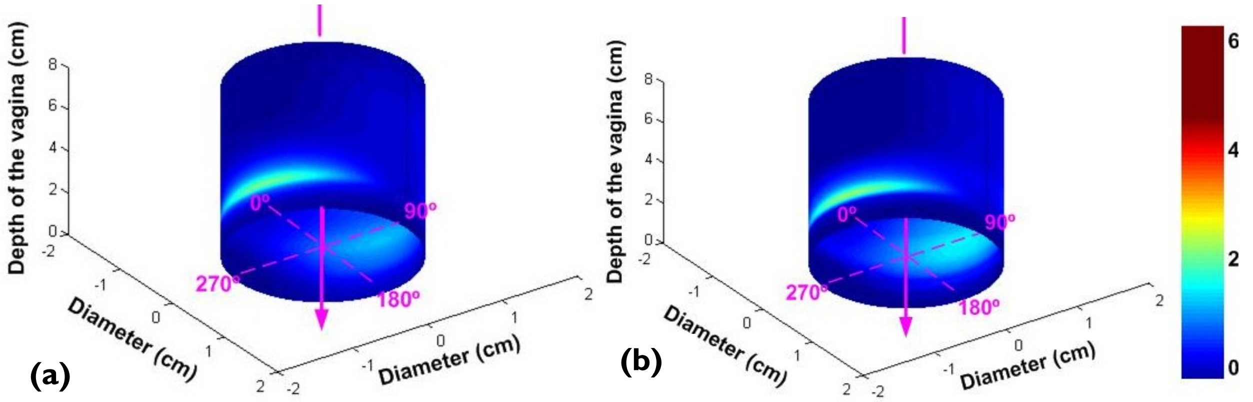


Figure 12.9: 3-D distribution of the pressures (a) at rest (b) during a 50% PFM contraction in SUI women. N= 10.

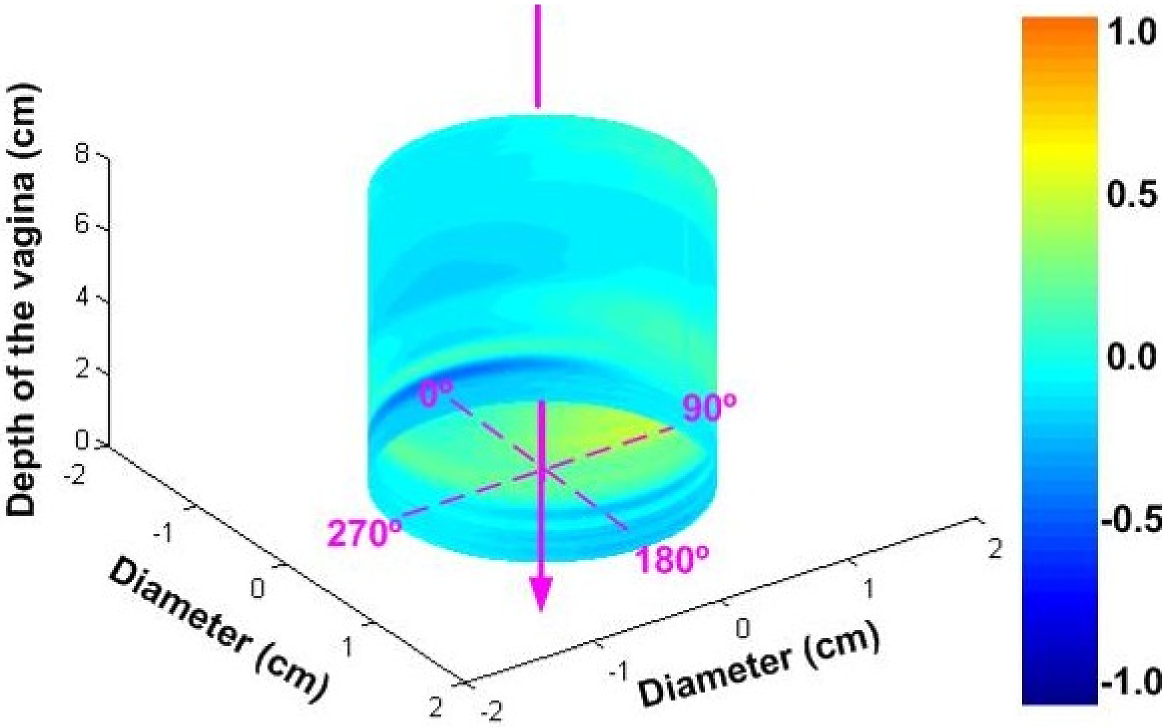


Figure 12.9c: Adjusted VPP between rest and 50% PFM contraction showing the 3-D distribution of the differences of the pressures in SUI women. N= 10.

12.5 Discussion:

The directionally sensitive mechanical probe was able to record VPP at rest and during a PFM contraction. In undertaking intra-vaginal PFM measurements it is appropriate to account for the influence of inserting the device as well as the compliance of the vaginal wall, and its capacity to transmit intra-abdominal pressures and forces generated by a voluntary PFM contraction. By accounting for the change in active and passive pressures, and measuring the differences between the posterior and anterior wall pressures, the VPP generated in the present study represents corrected measurements and a true reflection of the change in pressure in the vagina due to a PFM contraction. As discussed earlier, any instrument inserted into the vagina will have an effect on the pressures recorded, so it is difficult to directly compare studies however results are consistent with previous observations (Guaderrama *et al.*, 2005b;Morgan *et al.*, 2005). Comparison of our results with those reported by Morgan et al, indicate a reasonable agreement in resting vaginal closure pressure (VCF) of asymptomatic, continent women, VCF^{REST}, which was 3.6±0.8N versus 3.4±0.3N/cm^2 in the present study. Similarly, VCF^{MAX} was 7.5±2.9N for a maximum contraction compared to 4.18±0.26N/cm^2 for approximately half of the maximum strength. Using perfusion techniques (Guaderrama *et al.*, 2005b) demonstrated similar directional differences relative to the anterior/posterior plane and a peak pressure at a distance of 2cm from the introitus. Using a 1.5cm balloon device, measuring a mean pressure of its contact area, another study recorded the highest pressures at 3.5cm proximal from the introitus of vagina (Bo *et al.*, 1990a) A recent study also using corrected measurements was unable to localise pressure changes, however indicated that both the active force development and active stiffness in the PF was significantly reduced in incontinent women, whereas the passive resting mechanical forces in the PF in both groups were not different (Verelst & Leivseth, 2007). As this current study was able to differentiate between the pressures produced posteriorly and anteriorly, it indicated that there was also a significant difference at rest.

A significant limitation of this VPP study is the lack of any reliability testing. In addition to the small numbers within the SUI group, there is a difference in age between the control group and the women with SUI, which may have contributed to variance in the pressure measurements.

12.6 Summary:

The novel vaginal pressure probe has enabled the localisation and measurement of the pressure changes that occur in the vagina during a PFM contraction. The highest-closure forces occurred posteriorly located between the SP and UVJ and were predominately caused by the voluntary PFM contraction. Anteriorly, the profile curve was mainly influenced by the existence of the SP. Laterally there was a small incremental change registered by a PFM contraction. Vaginal pressures generated by a PFM contraction were significantly different between the continent and SUI groups.

Appropriate correction has been made to account for the effect of inserting a device into the vagina, as well as accounting for the baseline resting pressures. With future reliability and validity testing, this probe may provide a tool to quantitatively evaluate the passive and active properties of the pelvic floor and lead to greater understanding pelvic floor function and dysfunction.

The final experimental chapters return to the evaluation of the pelvic floor using 2D TP ultrasound imaging and image processing methods during two more manoeuvres commonly used in either the assessment or rehabilitation of pelvic floor function.

13 Effect of Valsalva on the Pelvic Floor; Evaluated by Real Time Ultrasound and Image Processing Methods

13.1 Introduction

Anatomically, urethral hypermobility is thought to be one of the main causes of female stress urinary incontinence (SUI), yet it is not only seen in patients with SUI, it is also evident in many continent nulliparous women (Peschers *et al.*, 2001a;Reed *et al.*, 2004). Typically urethral hypermobility is assessed during a Valsalva manoeuvre, which is a defined as forced expiration against a closed glottis, requiring contraction of the diaphragm and abdominal muscles, in order to obtain markedly increased intra-abdominal pressure (IAP)(Orno & Dietz, 2007).

It has been recently suggested that one of the main reasons why there is significant overlap in the amount of displacement of the urethra during a Valsalva, is due to the confounding involuntarily or voluntarily co-activation the pelvic floor muscles (PFM) (Orno & Dietz, 2007). However, co-activation of the PFM muscle and muscles surrounding the abdominal cavity is necessary to increase IAP (Hemborg *et al.*, 1985;Cresswell *et al.*, 1992) and in continent women PFM contraction rises proportionally to increasing IAP (Amarenco *et al.*, 2005). It has been reported that during a cough in continent women, bladder neck mobility was less than during a Valsalva even though there was greater IAP generated during a cough (Peschers *et al.*, 2001a). Furthermore, there were quantifiable differences in vesical neck mobility during a cough and Valsalva manoeuvre in continent women which was lost in the primiparous SUI women (Howard *et al.*, 2000).

As reported in Chapter 6, in continent women during a cough, there was evidence of a PFM contraction, which was absent in women with SUI. Perhaps during a Valsalva, in addition to intact fascial support, one of the reasons it is reported that there is less displacement of the urethra in continent compared to women with SUI, is the presence of an automatic PFM contraction which is lacking in women with SUI. The author suggests that rather than the involuntary PFM contraction being due to fear of involuntary passage of urine, wind or stool as suggested by Orno and Dietz, it is likely that a PFM contraction is a normal response to a manoeuvre that increases IAP.

The next experimental chapter describes the mechanisms of PFM function during a Valsalva in continent and SUI women and the effect on the urethra using transperineal (TP) ultrasound and image processing methods (IPM). It then compares the results from the cough in Chapter 6 to determine the differences in the response of the urethra to stress due to coughing and in the presence of a Valsalva manoeuvre.

13.2 Aims:

13.2.1 To describe the displacement of the ano-rectal angle (ARA) and the urethra during a Valsalva manoeuvre in continent and SUI women.

13.2.2 To compare the displacement values of the ARA and urethra during a Valsalva to those during a cough.

13.3 Hypotheses:

13.3.1 There is less displacement of the PF and urethra during a Valsalva in continent women, in part due to an involuntary contraction of the PFM and that this co-activation is absent in women with SUI.

13.3.2 In SUI women, due to the absence of a PFM contraction, the displacement of the urethra is similar between a cough and a Valsalva, whereas in continent women, the displacement values will be less during a cough.

13.4 Methods:

General methodology, data acquisition, ethical considerations and population sample have already been described in greater detail in Chapter 3.

Thirty three (33) female volunteers were asked to perform three consecutive Valsalva manoeuvres, held up to 5 seconds with a 5 second rest in between each one with the transperineal (TP) ultrasound transducer in position, in supine and if time allowed in standing too. A Valsalva manoeuvre was defined as a maximal straining effort, with forced expiration against a closed glottis. The degree of effort during the Valsalva was not standardized but subjects were encouraged to perform their maximal straining effort.

13.4.1 TP ultrasound, image processing methods and graph alignment:

Application of the ultrasound transducer (Section and 6.4.1); segmentation methodology for the urethra and relative position of the urogenital structures (Sections 4.4, 6.4.2 and 7.3.1); motion tracking algorithms for the symphysis pubis (SP) and ARA (Section 4.3, 6.4.2); have already been described. Graph alignment is at the start of the Valsalva manoeuvre.

13.4.2 Statistical analysis:

Comparisons within and between groups of the mean and Standard Error (SE) of the displacement of the Valsalva in supine and standing, and between a cough and a Valsalva were calculated and presented graphically. Statistical comparisons between groups using one-tailed unpaired t-tests were performed to evaluate the mean values (±2SD) and level of significant differences of the displacement, between the two groups.

Where the variances were unequal, Welch's correction was applied, and a level of $P < 0.05$ was considered significant. GraphPad Prism version 5.01 for Windows was used for statistical analysis.

13.5 Results:

One volunteer was excluded due to symptoms of overactive bladder (OAB) leaving thirty two (32) women available for analysis. The displacement of the urethra and ARA in twenty-three (23) continent women were analysed in supine, and sixteen (16) in standing. Nine (9) women with SUI were analysed in supine, five (5) in standing. ARA and urethral displacements were normally distributed in both the supine and standing positions.

The first section of the results will present comparisons between continent and SUI women performing a Valsalva, in supine, then in standing. Subsequently within group comparisons of urethral displacement during a cough and a Valsalva will be analysed.

13.5.1 Supine displacement:

There was statistically significant greater displacements of the ARA and both edges of the urethra in the SUI compared to continent group, the urethra in the SUI group was displaced at least 0.5 cm more than in the continent group (Table 13.1). Significant differences were found consistently in dorsal displacement of both the ARA and urethra:

there is negligible dorso-ventral displacement of the ARA in the continent group compared to over 0.5cm dorsal displacement in the SUI group; consequentially the angle of ARA displacement is very different between groups (Table 13.1 and Figures 13.1, 13.2).

Table 13.1: Mean and SD of the maximum displacements of ARA and urethra during a Valsalva in supine (mean ± SD, Unit: cm; Angle: degrees). (UV = Welch's correction applied for unequal variances) (ARA: Continent n = 23 and SUI n = 9)

	Dorsal	**Caudal**	**Resultant**	**Angle**
ARA				
Continent	-0.02 ± 0.07	-1.1 ± 0.48	1.1 ± 0.47	270 ± 11
SUI	-0.66 ± 0.49	-1.2 ± 0.53	1.4 ± 0.67	240 ± 11
P Value	**P = 0.002** (UV)	**NS** P = 0.25	**NS** P = 0.10	**P = 0.007** (UV)
Posterior				
Continent	-0.58 ± 0.46	-1.1 ± 0.26	-1.3 ± 0.46	250 ± 13
SUI	-1.2 ± 0.70	-1.5 ± 0.72	-2.0 ± 0.87	230 ± 20
P Value	**P = 0.02**	**P = 0.03** (UV)	**P = 0.009**	**P = 0.03**
Anterior				
Continent	-0.62 ± 0.53	-0.96 ± 0.38	1.2 ± 0.59	240 ± 13
SUI	-1.1 ± 0.74	-1.2 ± 0.63	1.8 ± 0.81	230 ± 21
P Value	**P = 0.03**	**NS** P = 0.14	**P = 0.02**	**P = 0.02**

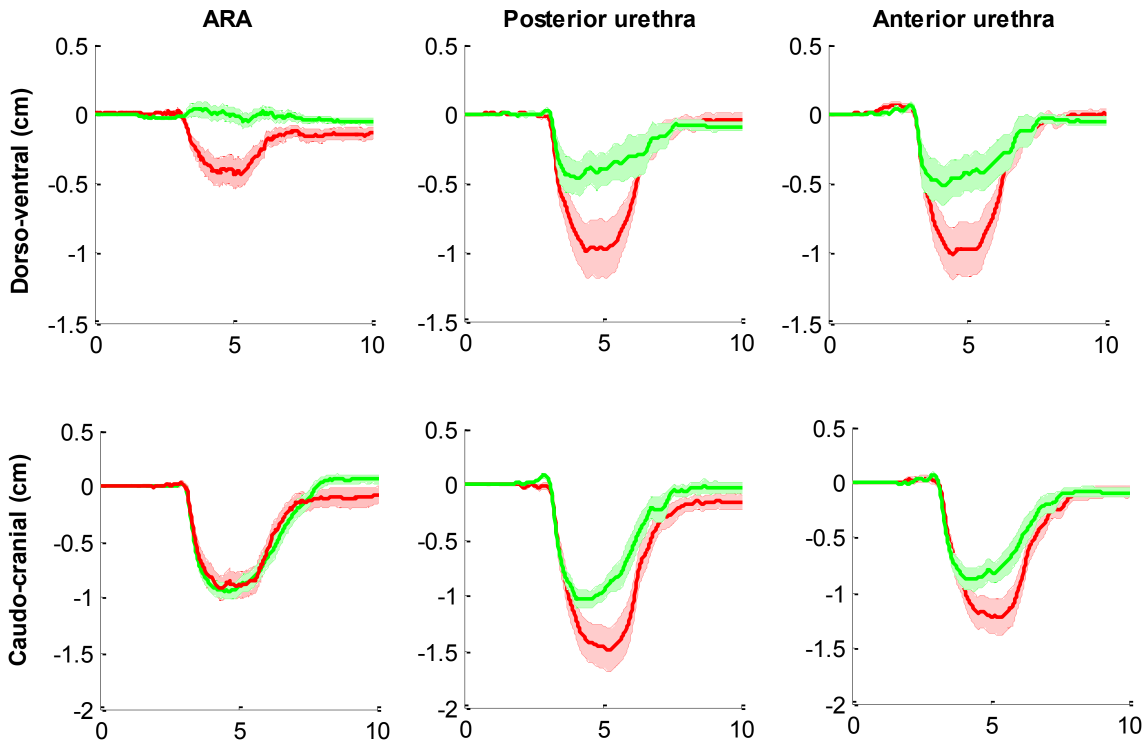


Figure 13.1: Comparison of the dorso-ventral and caudo-cranial displacements of the ARA, and both edges of the urethra during a Valsalva in supine: continent n = 23; SUI n = 9 women. The shaded area represents the Standard Error (SE).

Observing the trajectory of the ARA and urethra within groups illustrates how during a Valsalva, the SUI tissues behave in a similar manner, whereas the in the continent group, the ARA has a very different trajectory than the urethra (Figure 13.2). In addition, the urethra of the continent group appears to reach a finite dorsal displacement, before continuing more caudally. This "kink" is not observed in the SUI group.

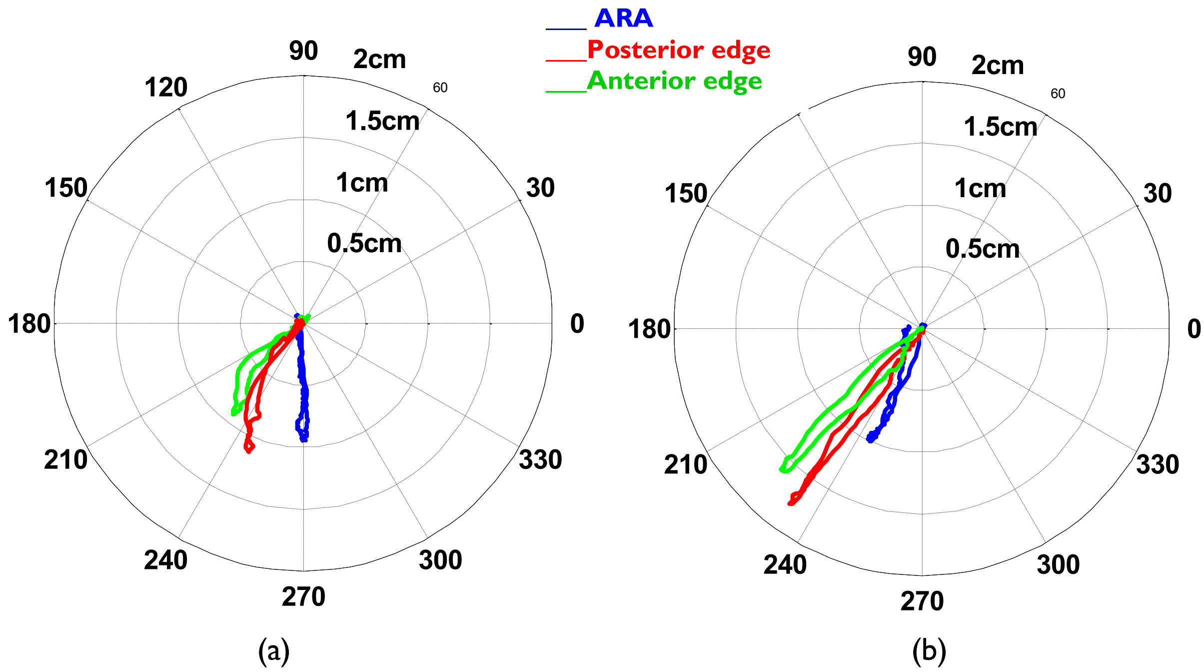


Figure 13.2: Comparison of the mean displacements of the ARA, and both edges of the urethra during a Valsalva in supine (a) continent n = 23; and (b) SUI n = 9 women. (Blue line = ARA; red line = posterior edge urethra; green line = anterior edge urethra).

13.5.2Standing displacement:

Measured from the original starting position, or zero reference point, both edges of the urethra were displaced less in the continent than in the SUI group, although due to the small numbers within the groups, this did not reach statistical significance (Table 13.2, Figures 13.3). Similarly, from a zero reference point, the displacement of the ARA is slightly larger in the continent group, but not significantly so. Unlike in supine, the displacement angles of both the ARA and urethra are very similar between groups (Table 13.2).

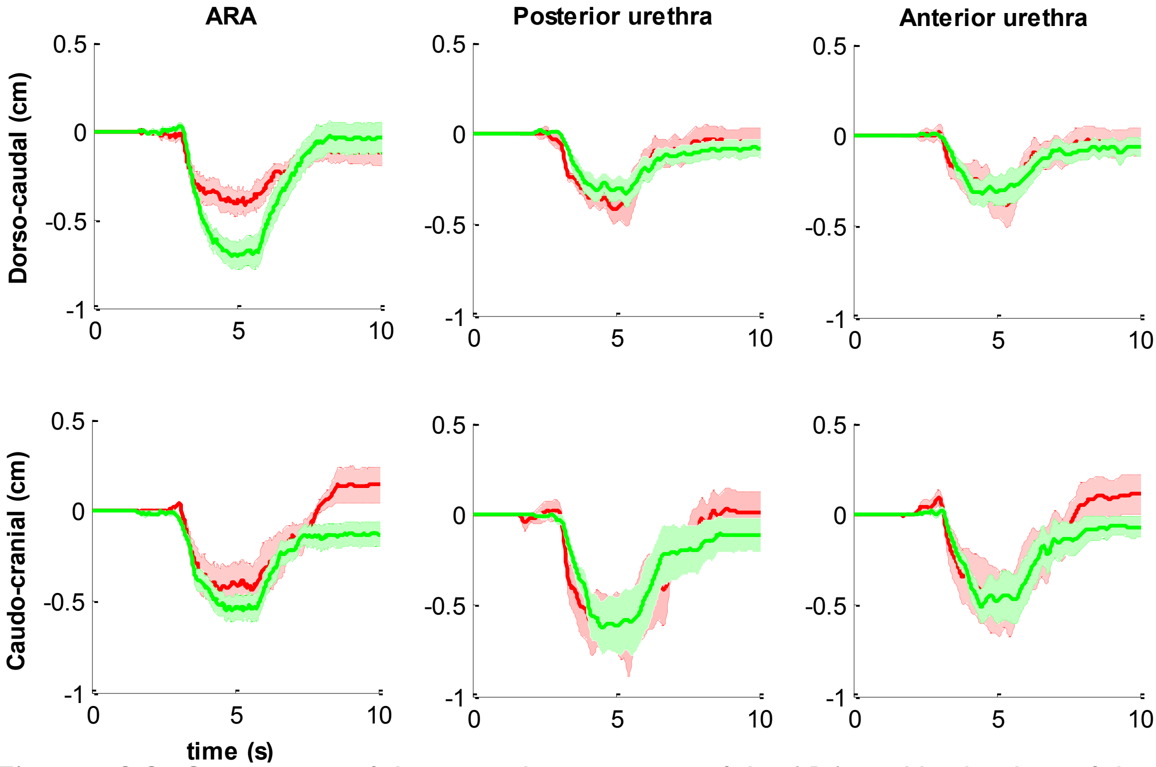


Figure 13.3: Comparison of the mean displacements of the ARA, and both edges of the urethra during a Valsalva in standing continent n = 16; SUI = 5. The shaded area represents the Standard Error (SE).

Table 13.2: Mean and SD of the maximum displacements of ARA and urethra during a Valsalva in standing (mean ± SD, Unit: cm; Angle: degrees). Continent n = 16; SUI n = 5.

	Dorsal	Caudal	Resultant	Angle
ARA				
Continent	-0.69 ± 0.36	-0.83± 0.48	1.1 ± 0.55	230 ± 14
SUI	-0.56 ± 0.21	-0.66 ± 0.51	0.9 ± 0.47	220 ± 20
P Value	**NS** P = 0.23	**NS** P = 0.25	**NS** P = 0.23	**NS** P = 0.24
Posterior				
Continent	-0.33 ± 0.18	-0.68 ± 0.46	0.77 ± 0.47	240 ± 15
SUI	-0.51 ± 0.34	-0.81 ± 0.44	0.98 ± 0.52	240 ± 16
P Value	**NS** P = 0.17	**NS** P = 0.33	**NS** P = 0.26	**NS** P = 0.47
Anterior				
Continent	-0.36 ± 0.19	-0.55 ± 0.32	0.66 ± 0.36	230 ± 9.1
SUI	-0.41 ± 0.26	-0.81 ± 0.42	0.95 ± 0.39	240 ± 18
P Value	**NS** P = 0.37	**NS** P = 0.15	**NS** P = 0.14	**NS** P = 0.24

13.5.3 Effect of posture on the pelvic floor during a Valsalva; relative starting positions:

The differences between groups and postures become more apparent when the relative starting positions are accounted for (Figures 13.4, 13.5). As discussed in Chapter 7, when a continent women stands up, the urethra drops in a dorso-caudal direction, which in part will affect the total amount of overall displacement measured. For example, during a Valsalva in standing, from a zero reference point, the urethra moved less than in did in supine, however accounting for the relative starting position, the urethra finishes in a much lower position in standing than it does in supine. Furthermore, in standing, the urethra in continent women did not descend as low as the urethra in the SUI group did in *supine*.

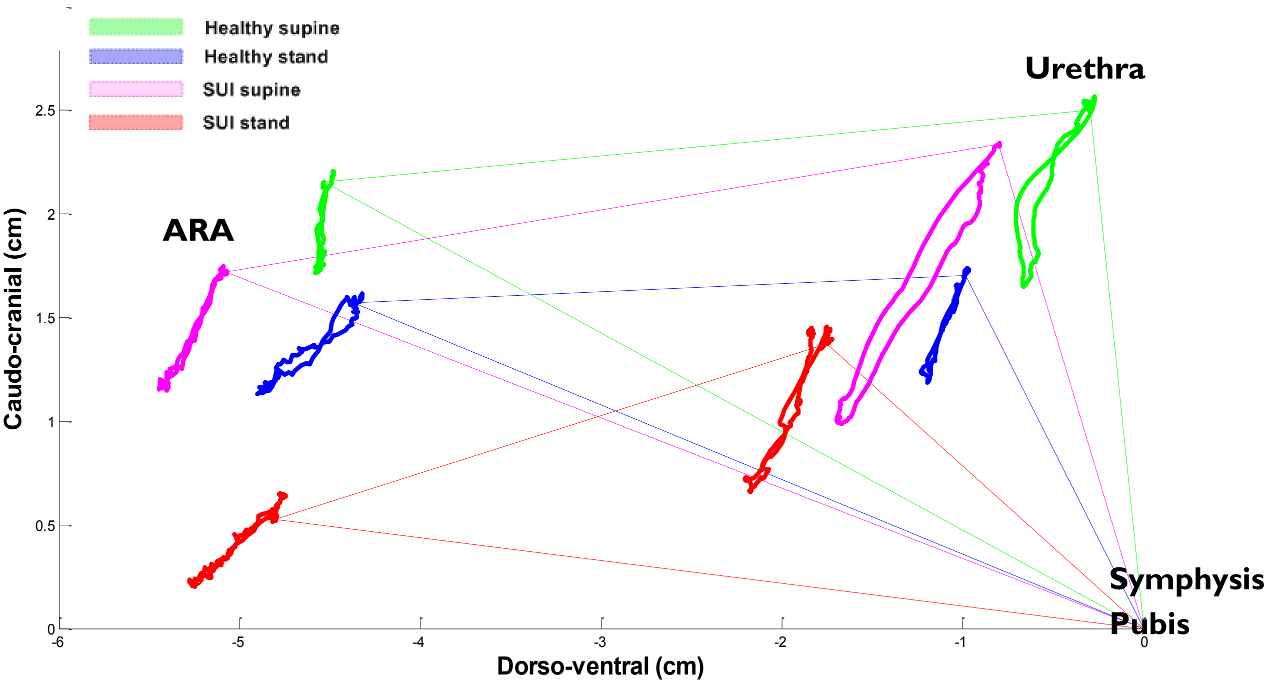


Figure 13.4: The relative starting positions and average trajectories of the urethra and ARA during a Valsalva in supine and standing: (green line continent supine n = 23: blue line continent standing n = 16: pink line SUI supine n = 9: red line SUI standing n=5).

Similarly from a zero reference point, during a Valsalva in standing, the urethra in the SUI group moves less than it did in supine; however it ends up in a more dorso-caudal position. Its position at the end of the Valsalva is at least 0.5 cm lower than that of the urethra of continent women.

The ARA of the SUI women also moves considerably in supine, and finishes even further dorso-caudally from the SP than the ARA of continent women in standing (Figure 13.4). Relative to the supine position, the ARA drops caudally a further 1cm in standing and during a Valsalva; the distance between it and the SP continues to elongate, finishing almost level with the SP caudally and almost 5.5cm dorsally away.

Calculating the changes in angle during a Valsalva between the various PF structures we observe that in continent women, the angles remain constant regardless of posture (Figure 13.5). For example during a Valsalva, whether in standing or supine and irrespective of the starting angle: the angle the UVJ makes between the ARA and SP increases by about 25 degrees; the angle the ARA makes with the UVJ and SP decreases by about 10 degrees. In SUI women however, the angle between structures reaches a similar degree in supine as well as standing. For example, the angle of the UVJ finishes at approximately 150 degrees in both postures, although it started at 100 degrees in supine and 125 degrees in standing; the angle of the ARA finishes at approximately 10 degrees, although it started at 27.5 degrees in supine and 20 degrees in standing.

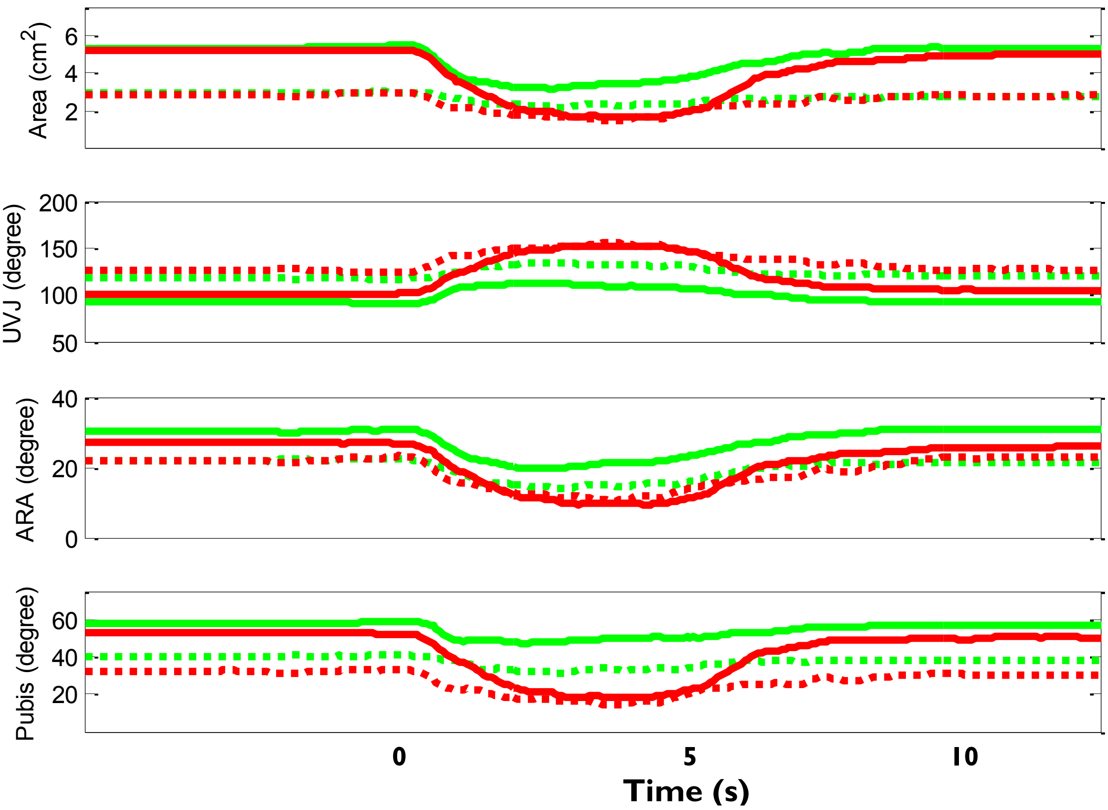


Figure 13.5: Area, UVJ angle, ARA angle, SP angle of the UVJ-Pubis-ARA triangle in Valsalva. Green solid line: continent women in supine; green dotted: continent women in standing; Red solid: SUI women in supine; Red dotted: SUI women in standing.

13.5.4Comparison of urethral displacement during a Valsalva and a cough:

When the amount of overall urethral displacement during a Valsalva was compared to that during a cough (Chapter 6); in the continent group, there was less displacement during a cough than Valsalva in both positions, although this only reached statistical significance in supine (Table 13.3). In the SUI group, where differences occurred, there was a non significant, slightly greater displacement during a cough. Comparing between manoeuvres in the SUI group, there were greater differences in the displacement of the anterior edge compared to the posterior edge.

Table 13.3: Mean and SD of the maximum displacements of the urethra during a Valsalva and Cough in supine and standing (mean ± SD, Unit: cm).
(Continent supine n = 23: standing n = 16: SUI supine n = 9: standing n=5).

	Continent		**SUI**	
	Supine	**Standing**	**Supine**	**Standing**
Posterior Edge				
Valsalva	-1.3 ± 0.46	-0.77 ± 0.47	-2.0 ± 0.87	-1.1 ± 0.52
Cough	-0.9 ± 0.28	-0.65 ± 0.34	-2.0 ± 0.71	-1.2 ± 0.46
P Value	**P = 0.003**	**NS** P = 0.27	**NS** P = 0.96	**NS** P = 0.72
Anterior Edge				
Valsalva	-1.2 ± 0.59	-0.66 ± 0.36	-1.8 ± 0.81	-0.96 ± 0.13
Cough	-0.8 ± 0.30	-0.59 ± 0.27	-2.1 ± 0.65	-1.2 ± 0.44
P Value	**P = 0.04 (UV)**	**NS** P = 0.31	**NS** P = 0.28	**NS** P = 0.34

13.6 Discussion:

This study characterises for the first time, the behaviour of the ARA during a Valsalva, both in supine and standing. It indicates that there are significant differences in behaviour of the PFM of continent compared to SUI women, although due to the small numbers in standing, differences are not statistically significant.

In both postures in SUI women, the urogenic structures all behave in a similar fashion, moving dorsal-caudally away from the SP in the direction expected from a passive stretch under influence of Laplace-type forces associated with raised IAP. In continent women however, there is a slight shortening of the distance between the ARA and the SP, and negligible dorsal-ventral displacement of the ARA in supine, which suggests that like in a cough, either there is a pre-planned activation of the PFM, or that the restoring forces of the PFM respond quickly to prevent any dorsal displacement. In standing, the direction and amount of ARA displacement is similar between groups. They are both displaced in the same direction as the urethra, although due to the more ventral starting position of the ARA of continent women, the PF of SUI women is elongated more.

The base of the PF, as defined from the ARA to the reference point on the SP, is shortened during a Valsalva in continent women in supine; elongated in the SUI group in supine and both groups in standing. In this current study, it can only be speculated whether the PFM are actively shortening, passively stretching or are actively lengthening during a Valsalva, as EMG studies were not undertaken. However it is less likely that they are passively lengthening as previous studies using surface electrodes EMG of the PFM has indicated a significant increase in EMG activity during a Valsalva (Thompson *et al.*, 2006a).

There is nothing in the literature to directly compare the displacement of the ARA on Valsalva in the continent group although a recent study examined the test retest reproducibility of SP ARA distance at rest and during a Valsalva in 18 women with urinary incontinence (Gottlieb *et al.*, 2009). Although the volunteers were in a side lying position and the authors did not define the type of urinary incontinence, their results (visit one: 1.1 cm ± 0.39 and Visit two: 1.6 cm ± 0.59 are reasonably consistent with our overall, resultant displacement values (1.4 cm ± 0.67) during a Valsalva. Their results help to support the validity of TP ultrasound and image processing methods to measure the displacement of the ARA using speckle tracking. One3D study, using both TP and transvaginal (TV) ultrasound has also investigated the effects of different modes of delivery on changes to levator hiatus distensibility, bladder neck mobility, and urethral sphincter volume (Toozs-Hobson *et al.*, 2008). The levator hiatus area was defined as the area bordered by the inferior border of the SP and the inner margin of the puborectalis, which is similar to the distance between the ARA and the SP in this current study. Vaginal delivery was strongly associated with a larger, more distensible levator hiatus and a greater degree of bladder neck mobility both antenatally and postpartum. As their ultrasound images were TV and 3D, the areas and angles calculated cannot be compared to the current 2D study.

It is clear that there is a cut off point in both groups where the stiffness of the PF is exceeded by the degree of pressure generated and the PF is no longer able to adequately resist the raise in IAP. Although the vaginal wall pressures taken using the intra-vaginal probe described in the previous chapter, were not measured at the same time as the ultrasound, during the Valsalva the uncorrected maximum anterior vaginal wall pressure in supine of SUI patients was similar to that of normal subjects (0.90 ± 0.26 (N/cm2) and

1.02 ± 0.19 (N/cm2)) respectively and in standing, the uncorrected vaginal pressures in SUI women were significantly less than the continent women (1.01 ± 0.23 (N/cm2) and 2.68 ± 0.22 (N/cm2) $P < 0.001$). As the displacement was comparable or greater in the SUI group, even though the vaginal pressure generated during a Valsalva was less than in the continent group, it suggests that the compliance of the PF is greater in women with SUI than in continent women. In future studies, if IAP is able to be measured concurrently, it may be possible to determine the cut-off value in both groups.

Further evidence of increased compliance in SUI women is the greater displacement, of approximately 0.5cm, of the urethra during a Valsalva. In supine, the displacement values of the urethra were comparable to those of other studies (Howard *et al.*, 2000;Peschers *et al.*, 2001a;Thompson *et al.*, 2007;Braekken *et al.*, 2008), helping to support the validity of our image processing methodology. However, there were also differences between other studies (Dietz & Clarke, 2001b;Kruger *et al.*, 2007;Reed *et al.*, 2004) most likely due to a combination of sample population and methodological differences. Of particular note, some authors choose to take a midpoint of the urethra, rather than one edge of the urethra-vesical junction and secondly to use the greatest value of Valsalva result rather than the average of all of the Valsalvas, which would have also increased our mean values.

The image processing methodology has also been able to describe the behaviour of the anterior and posterior edges of the urethra, and indicated that in both groups in supine and standing, there was generally greater movement of the posterior edge than the anterior edge. There were however, negligible differences in the dorsal direction in the continent group in both postures and the caudal direction in standing in the SUI group. It is suggested that in the continent group perhaps the dorsal displacement of the posterior edge is more similar to the anterior edge due to the extra ventral support or squeeze given from behind by the PFM, which is absent in the SUI group. The ventral squeeze may also be responsible for the "kink" observed in the trajectory of the urethra in supine, although it may also be due to urethral attachments to the SP. In standing however, the urogenic structures all move dorsal-caudally, including the ARA, and there is not a kink in the trajectory of the urethra. It would therefore be expected that in standing, as the urethra has already dropped dorsal-caudally, the effect of the urethral attachments would perhaps be more obvious.

Regarding the hypothesis that the PFM activity is the confounding reason why there are significant differences between displacement values of the urethra between studies (Orno & Dietz, 2007) it would seem logical that the group which would have greatest fear of incontinence would be the SUI, not the continent group. So by their rationale, the group most likely to have a reinforced voluntary PFM contraction during a Valsalva would be the SUI group, which is contrary to our study findings. However their study findings (Orno & Dietz, 2007) support our hypothesis that it is normal for the PFM of continent women to contract in response to rises in IAP in order to limit the amount of urethral displacement. They also discovered that if they trained their subjects to actively relax their PFM during a Valsalva, the urethra was displaced further. Our hypothesis is also supported by the comparison of urethral displacement values during a cough and Valsalva. As there is greater IAP generated during a cough than during a Valsalva, if the urethra and PF were just exposed to passive forces, one may have expected greater displacement values of the urethra during a cough than during a Valsalva. Howard et al also observed that there were quantifiable differences in vesical neck mobility during a cough and Valsalva manoeuvre in continent women which was lost in the primiparous SUI women (Howard *et al.*, 2000). However, it could be argued that since in continent women PFM contraction rises proportionally to increasing IAP the effect of the PFM during the Valsalva in standing should have been more obvious (Amarenco *et al.*, 2005). However as discussed earlier, there will be a limit to how much force the PFM can withstand without being displaced dorso-caudally, so until we can use concurrent EMG, it will remain speculative whether the PFM are actively lengthening or passively stretching. With change in posture, from supine to standing, vaginal closure force increases because of higher IAP and greater resistance in the PFM (Morgan et al., 2005). Two studies have compared the effect of a change of posture on the relative position of the BN and the effect of Valsalva on its displacement with TP ultrasound. Two studies have compared the effect of a change of posture on the relative position of the BN and the effect of Valsalva on its displacement with TP ultrasound (Meyer et al., 1996;Dietz & Clarke, 2001a). One other imaging study has compared the relative position of the PF organs in continent and SUI women in supine and standing (Meyer et al., 1996). Their control group was nulliparous volunteers, yet they supported this current study finding that the bladder neck (BN) drops down and back (caudo-dorsal) on assuming an upright position and the BN position at rest was lower in SUI women in both supine and standing.Comparable to our current study, there was less overall descent during a Valsalva in standing compared to supine but their displacement values were almost 1.0 cm greater. In addition, the final resting position of the bladder neck after a Valsalva was 0.3cm above the SP in both postures, whereas our current study indicated that the urethra was approximately 0.4cm lower in standing than in supine. Methodological differences aside, the pathology of their study group is unclear, which makes direct comparison more difficult. However another study with a group of mixed urinary incontinence used dynamic MRI and colpocystoproctography in the upright and supine positions and expressed similar displacement values of the bladder neck to ours (0.9 +/- 1.2 cm and 2.3 +/- 1.4 cm respectively) (Gufler et al., 2004). Finally, in continent women, the relative change in angle during a Valsalva between the various structures was constant regardless of posture which theoretically suggests that the PF of continent women works as an intact unit. In the SUI group, regardless of posture, the maximum angle between the various PF structures was constant, suggesting that the tissue reached its elastic limit in both postures. However this current study is unable to answer whether the limitation of angle or length change between the various PF structures is due to active forces in the form of neuro-muscular activity or passive restraining forces.

13.7 Conclusions:

Using TP ultrasound and image processing methods, we have been able to describe novel parameters of PF displacement during a Valsalva. In supine there is evidence of an automatic contraction of the PFM in continent women which is absent in women with SUI. The PF of SUI women is therefore more compliant than that of continent women, and subsequently the urethra and ARA are displaced further under comparable increases of vaginal pressure. In standing, there was insufficient power for differences to be statistically significant. The results for displacement of the urethra and ARA are consistent with other studies measuring the effect of a Valsalva on the PF, therefore supporting the validity of the image processing methods.

In continent women, there is evidence that in response to a Valsalva and a cough (Chapter 6) there is automatic activation of the PFM which helps to support the pelvic organs. Co-activation of the abdominal and PF muscles would be consistent with the model that predicts that muscles surrounding surrounding the abdominal cavity will work together in a coordinated manner to increase IAP and support the pelvic organs (Hodges *et al.*, 2007). The following chapter explores using TP ultrasound and image processing methods whether there is automatic activity of the PFM in response to an abdominal manoeuvre and whether there are differences between continent and women with SUI.

14 Effect of a Transversus Abdominis Contraction on the Pelvic Floor; Evaluated by Real Time Ultrasound and Image Processing Methods.

14.1 Introduction

The pelvic floor (PF) forms the base of the abdominal cavity or lumbo-pelvic cylinder (LPC) and as such the Pelvic Floor Muscles (PFM) contract not only to maintain continence, but to augment intra-abdominal pressure (IAP) and spinal stability (Hodges & Gandevia, 2000;Hemborg *et al.*, 1985;Pool-Goudzwaard *et al.*, 2004) (Chapter 2, Section 2.2). Co-ordinated co-activation of the PFM is therefore necessary in order to balance the functional demands of continence, respiration and lumbo-pelvic stability (Hodges *et al.*, 2007).

In a number of small studies, it has been shown that in continent women, voluntary abdominal muscle contraction is associated with PFM activity (Sapsford *et al.*, 2001;Madill & McLean, 2006;Neumann & Gill, 2002), yet it is unclear whether a similar pattern occurs in women with stress urinary incontinence (SUI). Activation of the abdominal muscles might contribute to the generation of a PFM contraction and consequently may affect the continence mechanism in women. Muscles of the LPC work at low levels at all times and increase their activity when the central nervous system can predict timing of increased load, such as occurs in coughing, lifting or limb movements (Constantinou & Govan, 1982;Moseley *et al.*, 2002a;Barbic *et al.*, 2003). It is known that in the presence of postural changes, respiratory demands, and pain, trunk muscle activity is altered (Moseley *et al.*, 2002b;Hodges & Richardson, 1998). If continence is to be maintained the PFM must contribute to ensure urethral and anal closure before the rise in IAP and consequently, in normal subjects, there is an increase in urethral pressure prior to an increase in IAP(Constantinou & Govan, 1982).

It has been shown that PFM activity is affected by changes in respiratory effort and postural challenge caused by rapid shoulder flexion and extension (Hodges *et al.*, 2007;Smith *et al.*, 2007a). Amongst continent women, PFM surface electromyography (EMG) showed increased activity before the onset of deltoid EMG activity and although delayed, postural PFM EMG amplitude was significantly greater in women with SUI ($p=0.010$)(Hodges *et al.*, 2007;Smith *et al.*, 2007a). Yet a further study by the same group, women with incontinence had increased PF and abdominal muscle activity associated with expected and unexpected loading, both prior to and during the postural response(Smith *et al.*, 2007b) . The authors did not provide any explanation for the conflicting reports, however as previously discussed (Chapter 2, Section 2.9) EMG activity can increase with an elevating or straining PFM contraction (Thompson *et al.*, 2006a) and therefore interpreting what the electrical activity of the PFM is reflecting, in terms of magnitude or direction of force generation, is particularly difficult when its action is not visible.

14.2 Aim:

To characterise the response of the PFM during voluntary abdominal manoeuvres, as computed by motion tracking of the ano-rectal angle (ARA) and urethra using 2D transperineal (TP) ultrasound and compare the response between continent and SUI women.

14.3 Hypotheses

14.3.1 There is automatic activation of the PFM in response to a low abdominal hollowing manoeuvre, which produces a voluntary transversus abdominis (TrA) contraction.

14.3.2 There is greater cranio-ventral displacement of the ARA and urethra in continent compared to women with SUI during a TrA contraction.

14.4 Methods:

General methodology, data acquisition, ethical considerations and population characteristics have already been described in greater detail in Chapter 3.

A low abdominal hollowing manoeuvre, which produces a voluntary TrA contraction, was taught and verified by both palpation and with transabdominal ultrasound. In crook lying, with one pillow under the head, the volunteers were taught to:

1. Visualise their deep abdominal muscles as a corset that wraps around their abdomen.
2. While breathing normally, place one hand above their umbilicus and one below, and slowly draw in their lower abdomen, as if they were pulling in their abdomen

away from their knicker elastic, with just sufficient magnitude that the volunteer and examiner could feel their deep abdominal muscles work and breathe normally.

3. Hold the contraction, whilst breathing normally for as long as they were able, up to a count of 5 seconds, and to repeat 3 times, with a 5 second rest period in-between, whilst any substitution strategies were discouraged (Table 14.1).

Table 14.1: Discouraged substitution strategies during a voluntary TrA contraction.

Movement of the trunk or pelvis out of a neutral position
Breath holding, apical breathing.
Drawing in of the upper abdominal wall.
Lateral flaring or bulging of the waist.
Excessive superior, inferior or lateral movement of the umbilicus.

In order to verify a TrA contraction using transabdominal ultrasound, the transducer head was placed transversely, midway between the iliac crest and ribcage, approximately 10cm either side of the umbilicus. Using the fingers, RLJ palpated immediately inferior and slightly medial to the anterior superior iliac crests, whilst the volunteer drew her lower abdomen in, palpating for symmetrical tensioning, without excessive bulging, underneath the fingertips.

With the TP ultrasound transducer in position, volunteers were asked to perform three consecutive TrA manoeuvres, whilst breathing normally, without instruction to contract their PFM, held up to 5 seconds with a 5 second rest in between each one in supine crook lying, and if time allowed in standing also. Simultaneous digital palpation of the low abdominal muscles verified activation of TrA.

14.4.1 TP ultrasound, image processing methods and graph alignment:

Application of the ultrasound transducer (Section and 6.4.1); segmentation methodology for the urethra and relative position of the urogenital structures (Sections 4.4, 6.4.2 and 7.3.1); motion tracking algorithms for the symphysis pubis (SP) and ARA (Section 4.3, 6.4.2); have already been described. Graph alignment is at the start of the TrA manoeuvre.

14.4.2 Statistical analysis:

Visual comparisons within and between groups of the mean and Standard Error

(SE) of the displacement of the ARA and urethra in supine and standing during a TrA contraction were calculated and presented graphically. Statistical comparisons between groups using one-tailed unpaired t-tests were performed to evaluate the mean values (±2SD) and level of significant differences of the displacement, between the two groups.

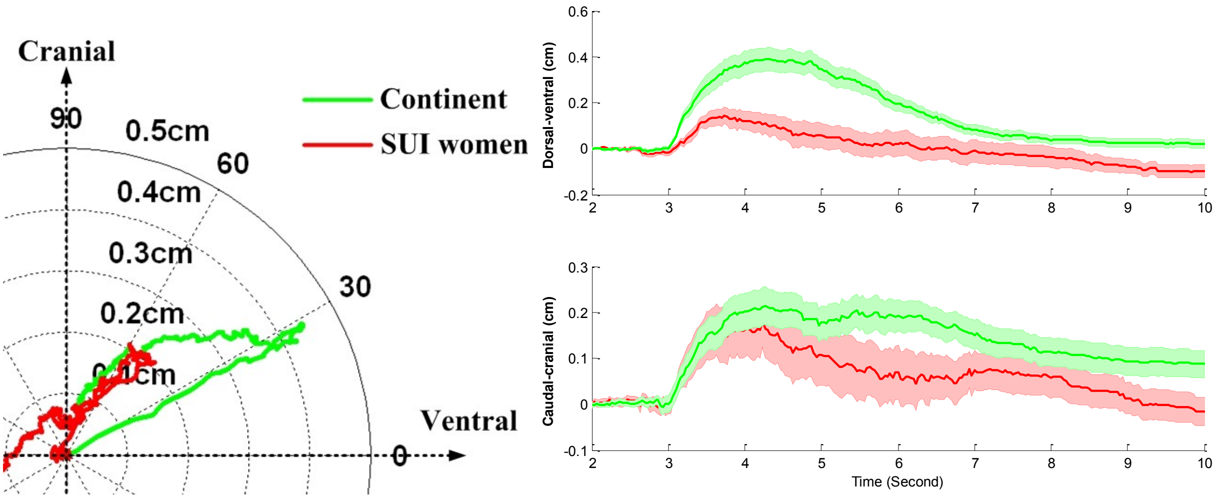
Where the variances were unequal, Welch's correction was applied, and a level of P < 0.05 was considered significant. GraphPad Prism version 5.01 for Windows was used for statistical analysis.

14.5 Results

ARA and urethral displacements were normally distributed in both the supine and standing positions. The first section of the results will present comparisons between continent and SUI women performing a TrA contraction, in supine, then in standing. Within group comparisons of PF displacement between the supine and standing postures will then be reported.

14.5.1 Supine displacement:

In both groups, it was found that there was co-activation of the PFM with a TrA manoeuvre as indicated by the cranio-ventral displacement of the ARA. (Figures 14.1)



(a) (b)

Figure 14.1: Comparison of the (a) trajectory and (b) dorso-ventral and caudo-cranial displacements of the ARA, during a TrA contraction in supine: continent (n = 23; green line) and SUI (n = 9; red line). The shaded area represents the Standard Error (SE).

However, there was significantly less ARA displacement in the SUI group compared with the continent group particularly in the ventral direction (Table 14.2). The co-contraction was sustained for longer in the continent group and the ARA finished at a higher position than at the starting point (Figure 14.1). The displacement of the urethra during a TrA contraction between groups was very similar, although in general, there was slightly greater displacement of the urethra in the SUI group, but this only reached statistical significance in the cranial displacement of the anterior edge (Table 14.2, Figure 14.2).

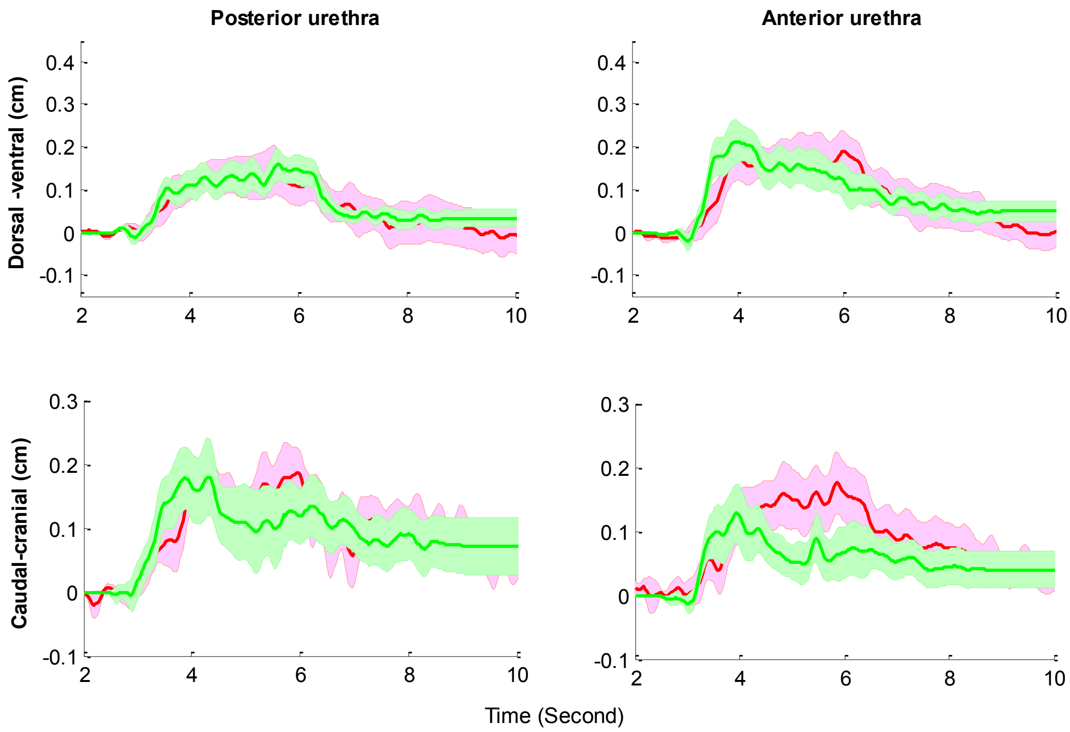


Figure 14.2: Comparison of the dorso-ventral and caudo-cranial displacements of both edges of the urethra during a TrA contraction in supine: continent (n = 5; green line) and SUI (n = 5; red line). The shaded area represents the Standard Error (SE).

Table 14.2: Mean and SD of the maximum displacements of ARA and urethra during a TrA contraction in supine (mean ± SD, Unit: cm). (UV = Welch's correction applied for unequal variances)(ARA; Continent n = 23 and SUI n = 9: Urethra; Continent n = 5 and SUI n = 5).

	Ventral	**Cranial**	**Resultant**
ARA			
Continent	0.39 ± 0.30	0.19 ± 0.23	0.51 ± 0.28
SUI	0.08 ± 0.18	0.13 ± 0.23	0.31 ± 0.12
P Value	**P = 0.004**	NS P = 0.26	**P = 0.005 (UV)**
Posterior			
Continent	0.20 ± 0.08	0.24 ± 0.16	0.34 ± 0.12
SUI	0.24 ± 0.10	0.31 ± 0.07	0.41 ± 0.05
P Value	NS P = 0.25	NS P = 0.18	NS P = 0.14
Anterior			
Continent	0.23 ± 0.14	0.15 ± 0.11	0.29 ± 0.16
SUI	0.29 ± 0.10	0.26 ± 0.07	0.39 ± 0.11
P Value	NS P = 0.25	**P = 0.04**	NS P = 0.12

14.5.2 Standing displacement:

In standing there was significantly greater displacement of the ARA in continent compared with SUI women, particularly in the ventral direction (Figure 14.3, Table 14.3). The endurance of the co-contraction was similar, and the ARA of both groups returned to the starting position.

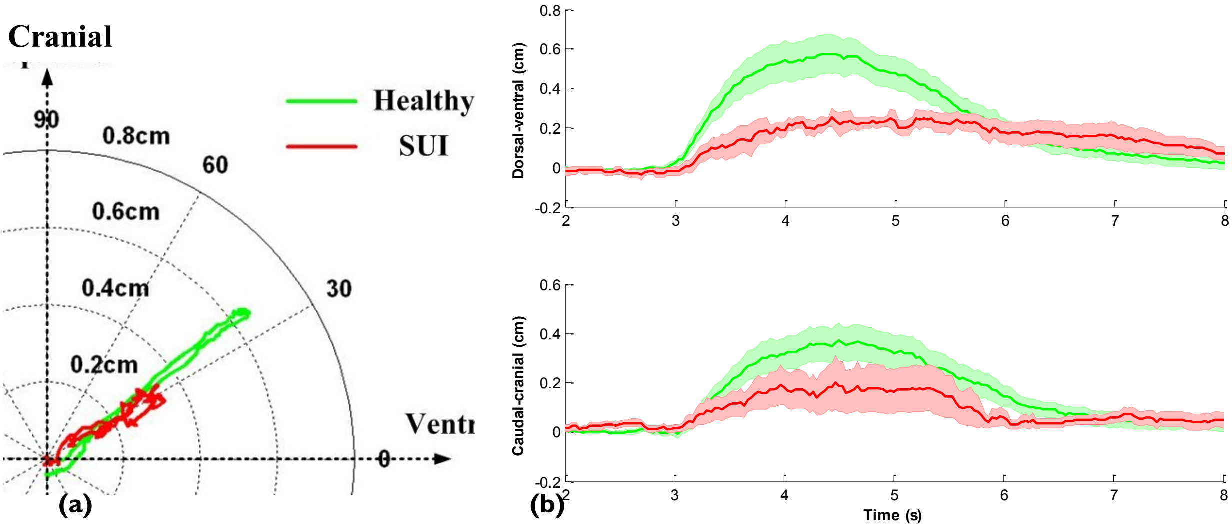


Figure 14.3: Comparison of the (a) trajectory and (b) dorso-ventral and caudo-cranial displacements of the ARA, during a TrA contraction in standing: continent (n = 16; green line) and SUI (n = 5; red line). The shaded area represents the Standard Error (SE).

Table 14.3: Mean and SD of the displacements of ARA and urethra at during a TrA contraction in standing (mean ± SD, Unit: cm). (UV = Welch's correction applied for unequal variances) (ARA: Continent n = 16 and SUI n = 5: Urethra: Continent n = 5 and SUI n = 5).

	Ventral	**Cranial**	**Resultant**
ARA			
Continent	0.52 ± 0.22	0.33 ± 0.17	0.67 ± 0.54
SUI	0.22 ± 0.087	0.17 ± 0.21	0.33 ± 0.11
P Value	**P = 0.012 (UV)**	NS P = 0.15	**P = 0.016 (UV)**
Posterior			
Continent	0.37 ± 0.73	0.42 ± 0.16	0.66 ± 0.65
SUI	0.17 ± 0.11	0.42 ± 0.22	0.45 ± 0.24
P Value	NS P = 0.28 (UV)	NS P = 0.48	NS P = 0.25
Anterior			
Continent	0.42 ± 0.71	0.29 ± 0.21	0.58 ± 0.68
SUI	0.19 ± 0.17	0.29 ± 0.23	0.33 ± 0.21
P Value	NS P = 0.24 (UV)	NS P = 0.48	NS P = 0.24 (UV)

As hypothesised, the urethra was displaced further in the continent group than the SUI group, particularly in the ventral direction, but due to the small number of subjects and variance within and between groups, this did not reach statistical significance.

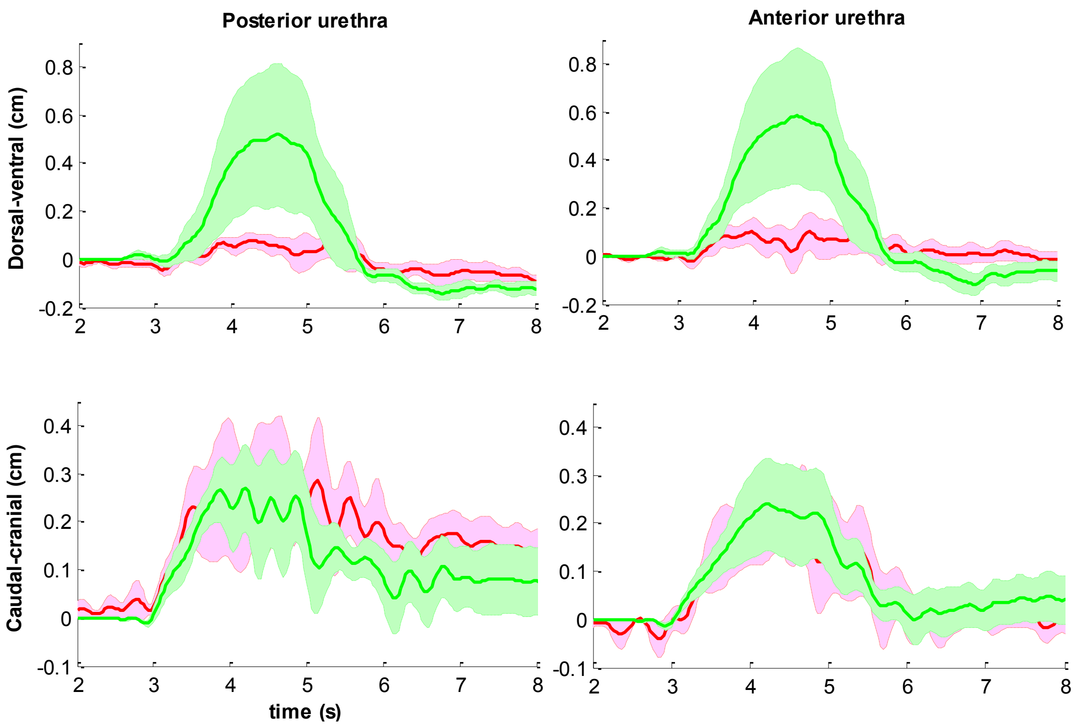


Figure 14.4: Comparison of the dorso-ventral and caudo-cranial displacements of both edges of the urethra during a TrA contraction in standing continent (n = 5; green line) and SUI (n = 5; red line) women. The shaded area represents the Standard Error (SE).

14.5.3 Comparison between ARA displacement in supine and standing:

In continent women, in standing, there was greater displacement of the ARA following a TrA contraction, compared to supine in both the ventral and cranial directions but this did not reach statistical significance (Tables 14.2 and 14.3 Figure 14.5).

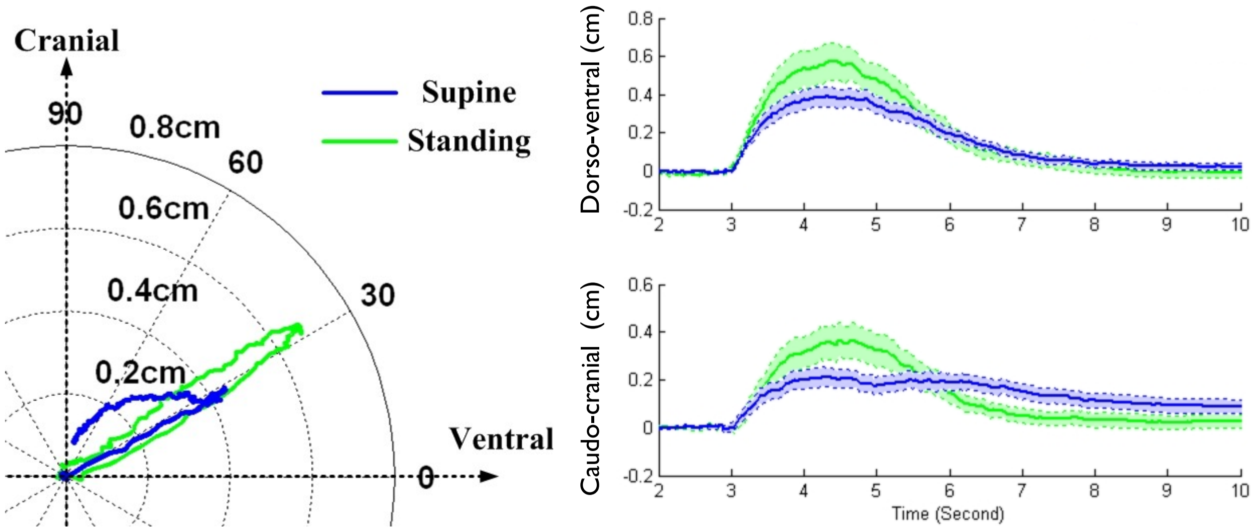


Figure 14.5: (a) Trajectory of the ARA movements of continent women in supine (n =23, blue) and standing (n =16, green). **(b)** Mean and Standard Error (SE) of the dorso-ventral and caudo-cranial displacement of ARA in supine and standing. The shaded area represents the SE.

In the SUI women, there were minimal differences in overall displacement with a change of position, although the endurance appeared slightly better in standing but there was greater variability within subjects in standing (Figure 14.6). In standing, the ARA did not return to the starting position, remaining more cranially placed.

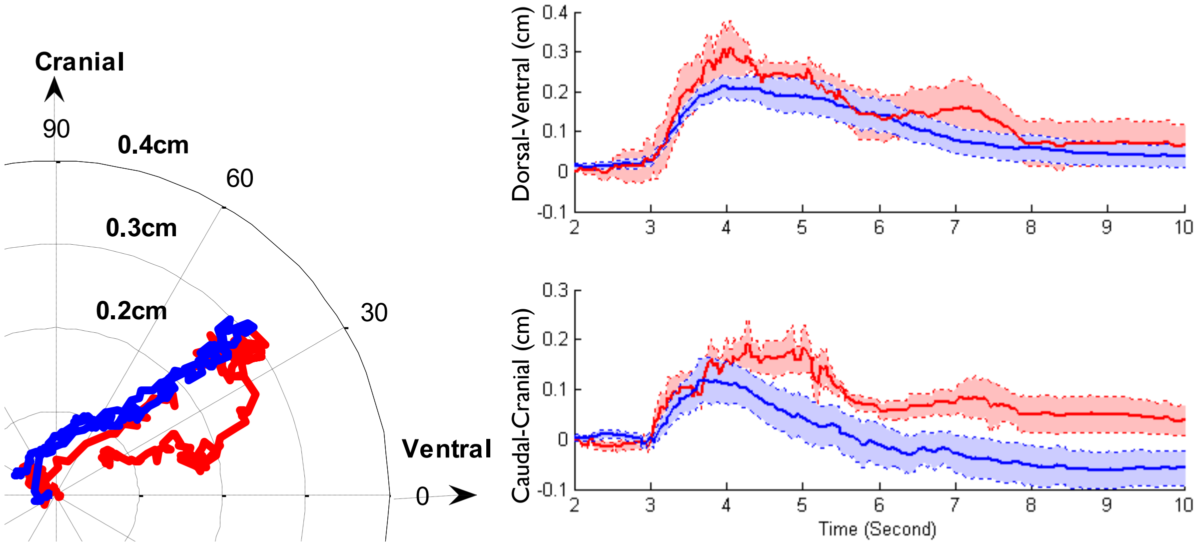


Figure 14.6: (a) Trajectory of the ARA movements of SUI women in supine (n =9, blue) and standing (n =5, red). **(b)** Mean and Standard Error (SE) of the dorso-ventral and caudo-cranial displacement of ARA in supine and standing. The shaded area represents the SE.

Once again, when accounting for the relative staring positions of the PF structures, the differences between groups and the effect of a change in posture on the PF structures became clearer (Figure 14.6). Although the ARA and urethra of the continent group were displaced more in standing than supine from a zero reference point, due to the lower starting position in standing, neither structure reached as high a cranio-ventral position in standing as they did in supine. Similarly from supine to standing, the PF structures of the SUI group dropped so far caudally, that the end position of a TrA contraction in standing, failed to reach the supine starting position.

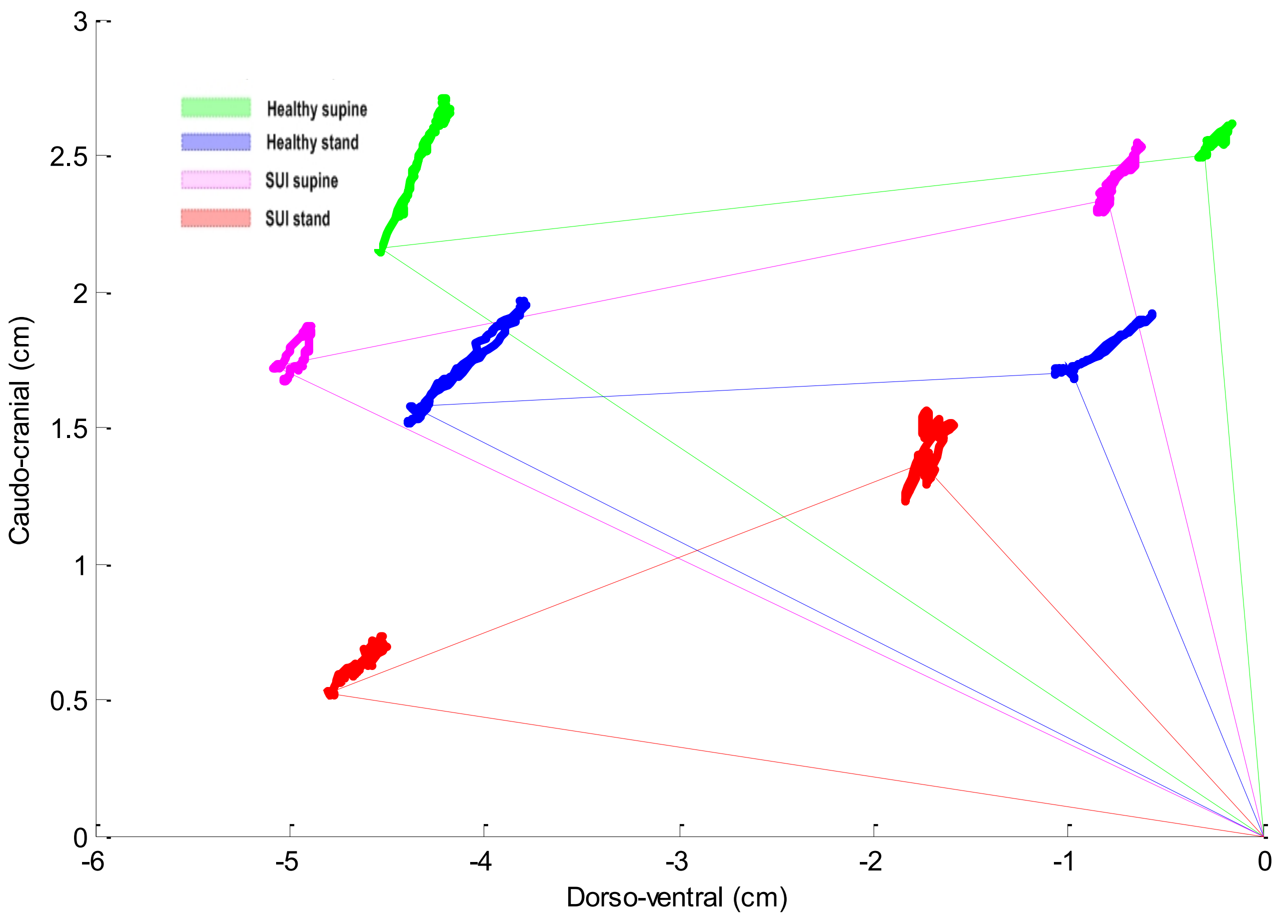


Figure 14.6: The relative starting positions and average trajectories of the urethra and ARA during a TrA contraction in supine and standing: (green line continent supine n = 23: blue line continent standing n = 16: pink line SUI supine n=9: red line SUI standing n=5).

14.6 Discussion:

This study has confirmed that contraction of the TrA automatically facilitates a contraction of the PFM in continent women and is the first study to characterise the cranio-ventral displacement of the ARA and urethra. It provides unique evidence of co-contraction in SUI women, and demonstrates that there is less ventral displacement of the ARA during abdominal muscle activity in supine and standing compared to continent women.

Displacement of the urethra during a TrA contraction in supine is more similar between groups, although unexpectedly in the SUI group there was significantly greater cranial displacement of the anterior edge of the urethra than in the continent group. In Chapter 11, during a PFM contraction in SUI women, the anterior edge appeared to shift cranially, independently of the posterior edge, however during a TrA contraction, there was simultaneous movement of the posterior edge of the urethra.

In standing, there was greater displacement of both the ARA and urethra in continent woman compared to the SUI group. A change in position from supine to standing resulted in almost twice as much displacement of the urethra and ARA in the continent group, but little difference in the SUI group. As discussed in the voluntary PFM experimental chapter (Chapter 10, Section 10.6), a greater displacement does not reflect an anatomically higher final resting position of either structure, as smaller displacements can be representative of higher resting tone in the PFM musculature and/or poor contraction of the PFM, and larger displacements due to a stronger contraction, or increased laxity in the connective tissue. If the IPM had not been able to determine the relative starting positions of the PF structures, it could have been concluded that in the continent group, a TrA in standing facilitates a stronger PFM contraction compared to the supine position. However, as the ARA and urethra are in a relatively lower position in standing compared to supine, the differences in displacements between positions in the continent group could just be reflective of the increase in available range from supine to standing due to the lower starting position of the pelvic tissues. Yet, in the SUI group, the change in position of the pelvic organs from supine to standing was even greater, leading to potentially greater displacement in standing compared to supine. As this lower starting position did not result in a significantly larger displacement during a TrA contraction in standing compared to supine, attributing the differences just to the relative starting position is somewhat limiting.

IAP is generated by co-activation of the PFM, the diaphragm and the abdominal muscles (Hemborg *et al.*, 1985;Hodges & Gandevia, 2000). Ventral displacement of urogenital structures produces compression of the urethra towards the symphysis pubis (SP), augmenting urethral closure pressure (Delancey, 1988). If the mechanisms of IAP generation and urethral closure pressure are both affected in SUI women, this could be another contributing mechanism by which the IAP exceeds urethral pressure facilitating leakage in incontinent women. In addition, the greater differences observed between groups in standing and supine, also contributes to our understanding of why women with SUI are more likely to leak in the standing position.

Smith (Smith *et al.*, 2007b) challenged the clinical assumption that incontinence was associated with reduced PFM activity with the observation that there was an increase in PFM and abdominal muscle activity during postural perturbation in SUI women, and suggested that training control and coordination of abdominal muscle activity may be important in treatment in SUI. Our study suggests that the co-ordination of muscle activity is present in both groups, so attempting to activate the PFM in isolation, as has been recommended in the past would appear non physiological (Laycock, 1992). However, even though there is less displacement of the PFM in the SUI group, this does not directly relate to differences of displacement of the urethra in supine, although in standing the differences are more apparent. Augmenting a PFM rehabilitation programme with an abdominal muscle training programme has not improved the treatment outcome in women with SUI (Dumoulin *et al.*, 2004c), therefore the usefulness of our current knowledge regarding co-activation of the PFM with, in particular the TrA muscle, is yet to be elucidated under research conditions. The clinical implication of our current study concludes that it is not appropriate to discourage the activation of the lower abdominal muscles when rehabilitating the PFM. Furthermore, if the patient is unable to voluntarily activate the PFM, our findings justify the clinical use of TrA to facilitate the PFM. However a more recent study using 4D ultrasound has indicated that in some women contraction of the TrA may open up the vaginal hiatus instead of closing it (Bo *et al.*, 2009). This current study did not support the finding indicated by Bo et al, as the sagittal distance between the ARA and SP was reduced during a voluntary TrA contraction. However as excessive generation of IAP during a more forceful abdominal contraction could easily create a caudal-dorsal displacement of the PF and urethra, indirect PFM training via TrA without confirming that there is an efficient co-contraction of the PFM is therefore not recommended.

14.7 Conclusions:

Using TP ultrasound and image processing methods, we have been able to describe novel parameters of PF displacement during a low abdominal hollowing manoeuvre, which produces a voluntary TrA contraction. There was an automatic activation of the PFM in response to a voluntary TrA contraction in both continent and SUI women. During a TrA contraction here was greater cranio-ventral displacement of the ARA in continent compared to women with SUI in supine and standing. In standing, there was greater displacement of the urethra in continent women compared to women with SUI, particularly in the ventral direction, but due to the small numbers analysed and unequal variances between groups, this was not statistically significant. In supine, during a

TrA contraction, there was significantly greater cranial displacement of the anterior edge of the urethra in women with SUI. Relative starting positions of pelvic floor structures needs to be accounted for as greater displacement does not reflect an anatomically higher final resting position of either the ARA or urethra during a TrA contraction.

The next general discussion chapter will relate the key findings of the methodological and experimental chapters to one another and to published literature, appraising both the implications and the limitations of the studies and making recommendations for areas of future research in this field.

15 General Discussion

15.1 Introduction

The aim of this research was to define new quantitative parameters of dynamic pelvic floor muscle (PFM) function using 2D transperineal (TP) ultrasound imaging combined with image processing methods (IPM). This chapter will start with the main impact of the current research followed by a discussion regarding the study population and design of the research. This will be followed by a critical appraisal, including the limitations of the measurement properties of TP ultrasound and IPM, relating whenever possible to other published literature on evaluation of the pelvic floor (PF). The chapter finishes by relating each of the experimental chapters to one another and to other published literature, in order to propose a model of optimum PFM function as well as presenting ideas for future research.

15.2 Main impact of study findings

TP ultrasound combined with IPM has enabled the dynamic evaluation of pelvic floor (PF) displacement throughout a whole manoeuvre, rather than limiting the quantification of displacement from static images at rest to the end of the manoeuvre. In this way, IPM have determined unique quantitative data regarding the automatic displacement, velocity and acceleration of the ano-rectal angle (ARA) and urethra during a variety of manoeuvres, and indicated that the displacement of the PF structures during automatic events demonstrate greater differences between groups than voluntary PFM contractions. IPM were also specific enough to differentiate between a cough and The Knack, a manoeuvre commonly used in the rehabilitation of women with SUI.

IPM was shown to be valid, specific and sensitive measurement tool, able to discriminate between continent and stress urinary incontinent (SUI) women. That the SUI group were only mildly to moderately incontinent and still produced such different patterns of movement to the asymptomatic group, hints of the potential usefulness of TP ultrasound imaging combined with IPM to be a valuable tool in greater understanding of normal PF mechanisms, providing the foundation for future studies with larger parity matched populations and potentially improve the rehabilitation of women with SUI and other PF disorders.

15.3 Study design and population

This was a cross-sectional, comparative study between continent women and women with SUI. It investigated the feasibility, reliability and validity of TP ultrasound imagining and IPM to investigate mechanisms and define new quantitative parameters of PFM function. As the study was primarily a proof of concept study a convenience sample of women with and without urinary incontinence was chosen from the general population of the San Francisco Bay Area. Although a convenience sample was also justified on the basis of limited financial, time and human resources, it resulted in unequal group sizes and a difference in parity between groups.

The volunteers described in this research, and their PFM function, support epidemiological studies that suggest that vaginal parity correlates with increased PF laxity, leading to SUI (Foldspang *et al.*, 1992;Rortveit *et al.*, 2001;Viktrup *et al.*, 2006). In addition to disruption of PF function as a result of damage during vaginal delivery, it is suggested that hormonal changes in pregnancy and the strain of the pregnant uterus lead to connective tissue remodelling and disruption of normal PF function (Lavin *et al.*, 1997). Furthermore, there are significant changes in PF and urethral anatomy in association with pregnancy whether delivered vaginally or by caesarean section (Toozs-Hobson *et al.*, 2008). Yet two thirds of parous women are continent (Hay-Smith *et al.*, 2008) and sister pair and identical twin studies have also reported that vaginal delivery is not associated with urinary incontinence, concluding that underlying familial predisposition toward the development of urinary incontinence may be present (Buchsbaum *et al.*, 2005;Buchsbaum & Duecy, 2008) There are a myriad of complex factors that lead to SUI, and a strong familial predisposition towards continence such as a strong PFM and/or strong fascia may preserve continence in multi-parous women. However, as it was beyond the scope of the present study to look at the effect of parity on either sample group, caution regarding the generalisability of this feasibility study is certainly warranted.

Although the investigators were blinded to the continence status of the volunteers the diagnosis of SUI was based upon self reported symptoms (Short form Incontinence Impact Questionnaire (IIQ-7) and Short form Urogenital Distress Inventory (UDI-6), rather than provocative clinical tests during uro-dynamic evaluation or pad tests. There was no access to uro-dynamic facilities, and took a pragmatic approach to standardizing bladder volume which may have affected the position and mobility of the urethra during manoeuvres (Schaer *et al.*, 1996;Dietz & Wilson, 1999). Manoeuvres were not standardised, such as measuring tidal volume for the cough, peak flow rate for Valsalva, electromyography (EMG) recordings for maximum voluntary PFM contractions and relied on the volunteer to do their maximum perceived cough, Valsalva, and PFM contraction. The SUI group are more likely NOT to give a maximum cough or Valsalva due to concerns of leaking, but they demonstrated more movement of ARA and urethra, however in future studies, standardising the testing procedures may strengthen any conclusions drawn. However recent evidence did suggest that a self subjective assessment was as good as doing a pad test and also correlated better with patient quality of life (Abdel-fattah *et al.*, 2004), so the utilisation of validated questionnaires seemed reasonable, and in a recent study using a standardised huff manoeuvre produced only a slight increase in intra-observer reliability (ICC 0.59 huff; 0.51 cough) (Braekken *et al.*, 2008). However, the opportunity to simultaneously measure EMG values or measurements of IAP may have resulted both in enhanced reliability and information regarding the timing of PFM contraction in relation to IAP the fatigue and displacement of the urethra and ARA.

15.4 Image processing methodology

Two methods of IPM were used, speckle tracking and segmentation and a combination of these techniques were able to capture the whole movement pattern of the PF even during fast automatic events such as a cough. In addition to producing a measurement tool able to produce reliable quantitative data from manoeuvres frequently utilised in either the assessment or rehabilitation of PF disorders, the ability to quantify and describe a functional manoeuvre likely to provoke incontinence in a vulnerable population was an important aim of this current study.

Speckle tracking was the most convenient, least time consuming IPM, able to track both the ARA and symphysis pubis (SP) in 15 to 30 minutes in a 300-frame ultrasound movie. Unfortunately it was unable to track the urethra during a cough as the urethra deformed too much, too quickly, especially in women with SUI. Depending on the quality of the images, segmentation took up to four hours to analyse and quantify the displacement of the urethra, SP and ARA. Segmentation to evaluate the whole of the PF was therefore not a feasible method, even though it potentially had the ability to extract greater detail than speckle tracking. Segmentation was subsequently only used to quantify the kinematic properties of the urethra and this typically took between 30 to 90 minutes for both edges of the urethra.

To date IPM such as speckle tracking, segmentation, elastography and strain rates using Doppler ultrasound have mainly been confined to echocardiology (Chapter 2 Section 2.10) so direct comparisons with previous PF imaging studies are limited to the changes in displacement from a position at rest and then again at the end of a manoeuvre (Chapter 2 Section 2.11). However whenever possible, throughout the following sections, there will be an attempt to relate the measurement properties of TP ultrasound and IPM and the results of the experimental chapters to other published literature on evaluation of the pelvic floor (PF).

15.4.1 Measurement properties of 2D TP ultrasound and IPM

TP and transabdominal ultrasound techniques associated with the PF have been confined to diagnostic anatomical variances and/ or the changes in displacement from a position at rest and then again at the end of a manoeuvre (Chapter 2 Section 2.11). No previous imaging study has attempted to define or describe a whole manoeuvre commonly used either for the assessment or treatment of PF disorders. 2D TP ultrasound and IPM allows quantification of the temporal sequence of both automatic and voluntary activities that activate the PFM. For example, prior to this current research, it was known that the Knack (a voluntary PFM contraction held prior to and throughout a cough) reduced the displacement of the urethra compared to a cough without pre-contraction, however, it is now possible to quantify and describe the whole of the manoeuvre rather than just compare the starting and finishing point of the urethra. In the future, the property of IPM to describe the whole of the manoeuvre may be an important property which determines whether or not the Knack is an effective treatment strategy for rehabilitation of SUI, or indeed other PF disorders such as prolapse. Furthermore, it is specific enough to inform us whether at the beginning of a treatment intervention, a patient already employs the Knack during a cough. IPM allows the quantification of the journey from A to B, rather than just the overall displacement that occurs from A to B. In other words, it is now possible to know how the structures arrived at the destination, and as in life, it may not matter how far the tissue (you) went, but how it (you) arrived there.

15.4.2 Reliability of IPM

The intra-observer reliability of the 2D TP imaging combined with IPM was excellent (ICC 0.94-0.99, SEM 0.01 to 0.08 cm) for segmentation of the urethra and good to excellent (ICC 0.67-0.96, SEM 0.03 to 0.12 cm) for speckle tracking of the ARA (Chapter 5, Section 5.4). This study was the first to report the inter-observer reliability of a cough and the ICC and SEM values were also good to excellent (ICC 0.61-0.90, SEM 0.04 to 0.25 cm) for urethral segmentation. Speckle tracking of the ARA also indicated substantial inter-observer agreement (ICC 0.58-0.96, SEM 0.03 to 0.23 cm), although in the dorsoventral direction ICC agreement was more variable (ICC 0.49 single measures, 0.66 average measures). As multiple assessments were used on a single subject, average measures is the most appropriate ICC value to interpret (Streiner & Norman, 1995;Landis & Koch, 1977). However ICC in isolation do not give a true picture of reliability, since it is just one point estimate of reliability based on one selected sample and confidence intervals (CI) should be reported (Bland & Altman, 1986;Bland & Altman, 1990;Rankin & Stokes, 1998;Stokes *et al.*, 2005;Teyhen *et al.*, 2007;Koppenhaver *et al.*, 2009) Although in the continent group, the 95% CI were narrow for both IPM methodologies (ranging from 0.55 →0. 97 to 0.97 →0. 99) the wider 95% CI in the SUI group emphasise the small numbers within this current study, and that future studies with greater power are necessary to have more confidence in the reliability.

Another major criticism of the ICC is that as they measure correlation the values can be high, even when one modality is systematically measuring larger values. Furthermore they are influenced by the between subject variance on the ratio, so if the true score variance is sufficiently large; reliability will always appear high and visa versa, revealing little information regarding the agreement between repeated measurements (Bland & Altman, 1986;Rankin & Stokes, 1998). ICC also cannot be interpreted clinically as they give no indication of the magnitude of disagreement between measurements. Bland-Altman analysis and plots, on the other hand, can identify systematic bias, are independent of the true variability in the observations and provide a clinically meaningful measure of the magnitude of agreement (95% limits of agreement) (Bland & Altman, 1986;Bland & Altman, 1990;Rankin & Stokes, 1998). Our current studies emphasise the caution required when interpreting ICC values alone as even in the dorsoventral displacement of the ARA, the difference between the observers was clinically insignificant with SEM values at less than 0.2cm, a standard deviation (SD) of the difference of 0.32cm and a bias of -0.06 cm.

To date, there are three ultrasound studies reported in the PF literature that have reported both ICC with CI and Bland and Altman analysis for reliability analysis of ultrasound imaging of the PF (Peschers *et al.*, 2001a;Yang *et al.*, 2009;Majida *et al.*, 2009) and two which have reported ICC and SEM (Thompson *et al.*, 2005;Gottlieb *et al.*, 2009) There are a further two that report reproducibility using Bland and Altman analysis (Pregazzi *et al.*, 2002;Armstrong *et al.*, 2006) and four more which report ICC with CI (Sherburn *et al.*, 2005;Athanasiou *et al.*, 2007;Braekken *et al.*, 2008;Braekken *et al.*, 2009). The remaining reliability studies report either ICC without CI or other statistical analysis such as Kappa statistics or an unnamed correlation coefficient with percentage errors (Reddy *et al.*, 2001;Weinstein *et al.*, 2007;Lewicky-Gaupp *et al.*, 2009).

Only two of these studies have evaluated the test-retest reliability of the displacement of the bladder neck (BN) during a cough (Peschers *et al.*, 2001a;Braekken *et al.*, 2008). The current study indicated excellent intra-observer reliability for displacement of the urethra (Chapter 5 Section 5.4.2.2): (ICC 0.97 to 0.99 average measures; with narrow 95% CI 0.85→0.99 to CI 0.97→0.99; SEM 0.01 to 0.08cm; mean difference ranged from -0.02 to 0.05 cm; SD_{diff} 0.02 to 0.47cm, and the 95% limits of agreement -0.46→0.07cm to -0.01→0.20cm. These reliability statistics are similar to the earlier study by Peschers et al who reported ICC 0.96 (95% CI 0.896 to 0.984), and a mean difference of 0.1cm with SD 0.2cm (Peschers *et al.*, 2001a). However, the more recent study, by Braekken et al, reported ICC 0.51 with very wide CI (95% CI 0.00 to 0.84). They did not report Bland and Altman analysis or SEM. Their 17 volunteers were termed healthy, (which may mean continent) and mean parity was 1.8 (range 0-4), which was similar to this current studies control group, whereas the study by Peschers et al were on a group of 20 continent nulliparous volunteers. This current study also indicates slightly better reliability analysis for continent women, however there were very little differences between the reliability of continent and SUI groups. Other differences were the mean period between tests. This current study repeated the measurements on the same recorded audio-visual image (AVI) files, so it is possible that repeating the entire examination at another date may result in lower repeatability. There was a mean period of 15.9 days between tests in the later study (Braekken *et al.*, 2008), whereas the study by Peschers et al repeated the manoeuvres after 15 minutes rest.

This current study used speckle tracking to account for the displacement of the symphysis pubis (SP) during a cough, and did not rely upon repeatedly determining the same point on the SP to take a reference point from; whereas the two previous studies used the same reference line as each other and the study by Braekken et al also reported having to exclude 35% of the images during a cough and the huff due to less than 50% of the SP being visible. It is not clear which % was removed from the cough or the huff.
To date there is only one study reporting the agreement between observers in evaluating a cough on TP ultrasound imaging (Lewicky-Gaupp *et al.*, 2009). The aim of their study was not to measure the displacement values but to determine whether a group of five experts in the PF imaging field could agree on whether the same AVI images were from continent or SUI women. They concluded that with existing methodologies, experts could not identify patterns of movement characteristic of SUI on ultrasound. 2D TP ultrasound imaging combined with IPM has the ability to reliably quantify the displacement of both the urethra and ARA during a cough and has sufficient sensitivity and specificity to distinguish between continent women and those with SUI. However as the numbers, particularly within the SUI group were small, further studies with larger power are required before being very confident of the discriminative ability of TP ultrasound and IPM.

15.4.3 Validity of IPM

The significant correlation between the measurements of ARA and urethral displacement during a voluntary PFM contraction and PFM strength measured using validated manual muscle testing (Laycock & Jerwood, 2001;Devreese *et al.*, 2004) supported the validity and use of these novel IPM and 2D TP ultrasound analysis in the assessment of PFM function (Chapter 11). Uniquely, this current study was able to separate the squeeze and lift component of the displacement caused by a PFM contraction, indicating that the ventral "squeeze" displacement of both the urethra and ARA, had a stronger association with strength of PFM contraction than the cranial lift.

The associations were comparable in both subgroups in all directions of displacement, although the SUI group had higher correlations (r_s = 0.67 to 0.84) between urethral displacement and digital evaluation of PFM strength than the continent group (r_s = 0.26 to 0.65). This trend was not observed in displacement of the ARA when in general the correlations of displacement and PFM strength, although significant, were lower.

Furthermore, when the subgroups were analysed, the continent group had statistically fair to moderate correlations (r_s = 0.39 to 0.51), whereas the SUI group indicated poor to moderate (r_s = 0.01 to 0.52), insignificant associations. As the urethral correlations were good to excellent and significant in the SUI group, the results of the ARA analysis cannot be solely attributed to the smaller sample size. Possible considerations are that:

1. Displacement of the ARA, by speckle tracking IPM is not as valid a measurement of PFM strength, as displacement of the urethra using segmentation IPM;
2. The confounders that create significant displacement without effective PFM strength, such as increased fascial laxity or deficits in the pubovisceralis muscle, have a stronger effect at the ARA than at the urethra.

Clearly a combination of the both factors could be responsible for the apparent differences. Until speckle tracking IPM can be improved sufficiently to be able to trace the urethra so that speckle tracking and segmentation can be directly compared, and further studies with higher power are undertaken, there will not be a definitive answer. However, in support of the first suggestion, one 3D transvaginal ultrasound imaging study indicated that when the methodology for measuring the displacement between the urethra and SP and change in length of the vaginal hiatus measured from the ARA and SP were the same; the displacement of the ARA had a higher correlation with digital strength measurement (r = -0.348), than urethra displacement (r = 0.19) (Yang *et al.*, 2009). Yet in contrast, two other 2D TP studies, displacement of the urethra had higher correlations with PFM strength than the study by Yang et al (Dietz *et al.*, 2002;Thompson *et al.*, 2006b) (r = 0.52 to 0.58) which were also comparable to values obtained in this current study. Furthermore, in a later 3D study, Dietz et al also indicated a weaker association with changes in hiatal length (measured from the SP to ARA) during a PFM contraction than urethral displacement, to digital strength measurements (r = -0.32) (Dietz *et al.*, 2006) Although the trend for higher associations with segmentation of the urethra compared to speckle tracking of the ARA was also observed in the continent group, there are a number of observations in support of point 2; that the displacement of the ARA maybe more affected by possible confounders than urethral displacement. Should the pubovisceralis not be intact, or the urethra or bladder be prolapsed, which is more likely in the SUI group, a voluntary PFM is less likely to displace the BN. Theoretically there could be large ARA displacements without concurrent urethral displacements. In the continent group, a greater displacement of the ARA implies greater displacement of the urethra (Chapter 11, Section 11.4.4). However in women with SUI, the more moderate and occasionally insignificant correlations between ARA and urethral displacements emphasises that the lack of displacement of the urethra, does not necessarily imply lack of movement of the ARA or visa versa.

Additionally, when both IPM are correlated with the Functional scale; a digital vaginal scale developed by the author (RLJ) which measures displacement and function of the PFM rather than strength (Chapter 9); there are statistically significant fair to excellent associations with both speckle tracking of the ARA and segmentation of the urethra for both groups (Chapter 11, Section 11.4.3). The Functional digital palpation scale was devised in order to determine, without the availability of ultrasound, the ability of the PFM to provide external support of the urethra during a cough. It is a simple, reliable digital palpation scale that distinguishes between continent women and women with SUI, and establishes the usefulness of a voluntary PFM contraction. As the Functional scale accounts for differences in individual anatomy and muscle function, it therefore reasonable to suggest that the higher correlations between digital strength of contraction and urethral displacements compared to digital strength of contraction and ARA displacement maybe attributable to intact anatomy rather than the different qualities of the two different IPM.

15.4.4 Other qualities of IPM

TP ultrasound combined with IPM is a valid measure of PFM function but as other imaging studies have indicated, the correlations with digital palpation scales of strength were moderate, suggesting that greater displacement of the PF is not an extremely sensitive measure of PFM strength (Dietz *et al.*, 2002;Sherburn *et al.*, 2005;Dietz *et al.*, 2006;Thompson *et al.*, 2006b;Yang *et al.*, 2009). However, as this present study has indicated, strength of voluntary PFM contraction is not the only quality of PFM function that is different between continent and SUI women. IPM combined with TP ultrasound imaging enables quantification of the displacement, velocity and acceleration of the urethra and ARA throughout the whole manoeuvre, and therefore is a very functional measurement tool. It gives an indication of the overall direction and displacement of the PF, irrespective of pathology or muscle activation patterns. For example, during a cough and Valsalva, the displacement, velocity and acceleration of the ARA indicates that there is either an automatic contraction of the PFM during activities that are known to increase the intra abdominal pressure (IAP) or the stiffness of the PF is greater in continent than women with SUI.

In order to verify the timing associated with displacement and PFM contraction, the IPM would need to be repeated in combination with electromyography (EMG) studies, however, the strain on the PF during a cough, derived from displacement and velocity values, was able to be calculated in supine and standing (Chapter 7, Section 7.4.2) (Rahmanian *et al.*, 2008). Women with SUI have a much larger strain imposed on the PF during a cough than continent women.

One other PF imaging study has also attempted to quantify the strain on the PF during manoeuvres. Using TP 2D and 3D ultrasound techniques, static measurements from the ARA and urethra to the SP were taken at rest and then again at the end of a Valsalva and PFM contraction and used to estimate the strain of the PFM by mathematical equations (Thyer *et al.*, 2008). Despite difficulties associated with the repeatability of determining the same position on the PF structures to take a reference point from, ICC between 0.65 and 0.85 were reported as well as a clinically insignificant small bias between operators. The validity of their method was also established using correlation with digital palpation, indicating a weak (Valsalva $r_s = -0.224$, $P = 0.033$) to moderate (PFM $r_s = 0.439$, $P < 0.0001$) Spearman correlation. Although their measurements were static and measured just two points at the beginning and end of the manoeuvres, their calculations were in principal similar to those described in calculating the strain over time in this present study. As they calculated the strain during a voluntary PFM contraction and Valsalva, the values cannot be directly compared.

Another quality of IPM combined with TP ultrasound imaging is the ability to determine at which point in the manoeuvre, the PF is unable to resist the dorsal or caudal displacement caused by an increase in IAP. For example during a Valsalva in supine (Chapter 13), the PF of continent women were able to resist dorsal displacement (or an increase in sagittal hiatal diameter), whereas in standing, the PF was elongated in a dorso-ventral direction, presumably due to the extra IAP generated during a Valsalva in standing. As discussed in Chapter 13, Section 13.6, although the intra-vaginal pressure probe did not record simultaneous readings, in continent women, the uncorrected pressure generated in standing was over twice as much as in supine, but the overall amount of displacement was the same, although the direction changed. In the SUI group however, both the pressure generated and the direction of ARA displacement was similar in both supine and in standing, yet there was a mean of 0.5cm more displacement in the supine position. Since IPM had been able to verify the relative starting positions of the PF structures in both groups in supine and standing, it was clear to see that the PF of SUI women in standing was much caudally placed at the end of the Valsalva than in supine.

One other imaging study has quantified the relative displacements of the PF in supine and standing during a Valsalva (Dietz & Clarke, 2001a). The power of the study was much greater than this present one (n = 132); however, it also indicated very similar displacement values. Both studies indicated that in supine, the BN started higher (mean 0.5cm) than in standing, and there was an increase in overall displacement (mean 0.5cm) of the BN compared to standing. However, in the study by Dietz et al, the final resting position of the BN after a Valsalva in supine was almost identical to the end position in standing; whereas this current study indicated that the final resting position of the urethra in standing was almost 0.5cm lower. Until measurements using IPM are acquired with significantly greater numbers than this present study of volunteers, significant caution is warranted in the generalisability of any results.

15.4.5 Limitations of IPM

Technical and methodological limitations of IPM and suggestions for future studies have already been given and discussed in detail (Chapter 5, Section 5.5.2). The following section describes the properties of the PFM that 2D combined with IPM is unable to quantify. The future studies section (Section 15.5) also discusses the measurement properties of TP 2D ultrasound and IPM still required to be evaluated.

As discussed earlier (Chapter 11, Section 11.5.6 and Chapter 15, Section 15.4.3), although there is a fair to good correlation between displacement of the ARA and urethra to the strength of PFM contraction; due to confounding variables such as fascial laxity and resting PFM tone, strong contractions can result in little PF displacement, and conversely weak contractions can result in large displacements (Chapter 11). Consequentially it would be naive to suggest that ultrasound imaging was able to even indirectly measure the strength generated by a voluntary PFM contraction. Strength training has been shown to be an effective treatment for SUI although the strength of the PFM does not significantly improve (Dumoulin & Hay-Smith, 2008). Additionally there are a number of women with SUI who have a strong voluntary PFM contraction or greater PFM activity (Theofrastous *et al.*, 2002;Morin *et al.*, 2004a;Smith *et al.*, 2007b), and conversely those with a weak PFM contraction who are continent (Miller *et al.*, 1998). However, until proven otherwise, as evidence based practice for rehabilitation of SUI indicates strength training is effective; the requirement to measure this property of the PFM is appropriate.

As discussed earlier (Chapter 2, Section 2.11.4) a more definitive identification of the mechanisms involved in continence functions could potentially be made using 3D ultrasound imaging, however the current frame rates obtained with 3D imaging are too slow to capture sufficient images during a cough. TP 3D studies have recently been shown to reliably reproduce detailed images of the vaginal hiatus in the axial plane (Braekken *et al.*, 2008;Braekken *et al.*, 2009;Weinstein *et al.*, 2007;Yang *et al.*, 2009). These images are beyond the scope of current 2D TP imaging techniques although the 360 degree transvaginal probe can reliably reproduced detailed morphology and hiatal area in the axial plane (Athanasiou *et al.*, 2007). In the future, the frame rate of volumetric imaging may improve sufficiently enough to allow detailed analysis of the displacement of the PF during dynamic events, but for now, only 2D ultrasound has this capability.

15.5 Optimum PFM function: the big picture

The results of each separate study have shown a difference in PF response between continent and SUI women to various physical events. In some cases the differences were not statistically significant and this may have been due to a number of factors, such as the small numbers in some groups. Although this reduces the ability to transfer the information to a similar population, and may be a limitation in the value of the study, it has clearly demonstrated a new way of assessing the PFM and provides the foundation for future studies with larger parity controlled populations. With these limitations in mind, the next section brings the experimental chapters together, drawing on the available literature, to provide a model of optimum PFM function and suggest a theoretical framework for future PFM rehabilitation.

15.5.1 Static supportive function: stiffness of the PF.

Within the bony pelvis, the pelvic organs are supported by fascia, connective tissue restraints and the PFM (Chapter 2, Section 2.2). This study indicated that the urethra and ARA of continent women were held higher and in a more ventral position relative to the SP than that of women with SUI, and when assuming the standing posture, descended less, suggesting that the PF and urethra of continent women is better supported than that of SUI women (Chapter 7). One other imaging study has compared the relative position of the BN in continent and SUI women in supine and standing (Meyer *et al.*, 1996). Their control group was nulliparous volunteers, yet they supported this current study reporting that the BN drops down and back (caudo-dorsal) on assuming an upright position and the BN position at rest was lower in SUI women in both supine and standing. One other study has also examined the influence of posture on the urethra using TP ultrasound imaging in 132 women with a mixture of lower urinary tract symptoms and concluded that the position of the bladder neck at rest is lower in a standing compared to a supine position(Dietz & Clarke, 2001a) (Chapter 7 Section 7.5.2 and Chapter 13, Section 13.6).

This current study also indicated that in the continent group, from a supine to standing posture, the starting position of the ARA did not descend so far as the urethra, most likely due to the greater connective tissue and muscular support of the PFM. A change in position of the ARA will represent both active muscular changes due to the presence or absence of a PFM contraction, as well as the passive tissue restraints. In this current study, not only did the ARA of SUI start in a more caudo-dorsal position than that of the continent group in supine, on assuming the standing position, the ARA of the SUI group did drop significantly, implying that both the passive tissue restraints and active PFM control provides less support to the PF (Chapter 7). In continent women, it has been shown that a PFM contraction rises proportionally to increasing IAP (Amarenco *et al.*, 2005) and vaginal closure forces increase in standing because of higher IAP and greater resistance in the PFM (Morgan *et al.*, 2005). However EMG studies in standing have also indicated greater PFM activity in women with SUI compared to their age, body mass index, and parity matched continent controls, which emphasises the caution required when interpreting the meaning of increased EMG activity when the action of the muscle cannot be visualised (Smith *et al.*, 2007b). Possibly the starting position of the ARA in the continent group did not descend so far due to the greater increase in effective activity of the PFM in continent women in response to the change in posture. To date, there are no other imaging studies that have investigated the effect of posture on the position of the ARA. Future studies combining EMG and imaging would enhance our understanding of the effect of a change in posture on the PFM.

15.5.2 Strength of PFM contraction:

In this current study, both digital examination and pressure measurements using a novel multidirectional intravaginal probe were taken in order to evaluate the strength of the PFM. As discussed earlier (Chapter 12), the force measured is always a sum of active and passive forces from the PFM, the smooth muscle in the fasciae and vaginal wall and passive mechanical forces from the connective tissue (Verelst & Leivseth, 2004b;Peng *et al.*, 2007c;Verelst & Leivseth, 2007). However, the major contributor to the active force component measured by any intravaginal device, whether a finger or a probe, is the pubovisceralis, and therefore the stronger the PFM active contraction, the stiffer the active force (Verelst & Leivseth, 2004b;Peng *et al.*, 2007c;Verelst & Leivseth, 2007). A stronger PF will therefore provide more resistance to dorso-caudal displacements created by increases in IAP, such as a cough or Valsalva or even by assuming an upright posture, thereby limiting the strain on fascial attachments.

Despite the view of some who question the reliability of digital examination of PFM contraction (Bo & Finckenhagen, 2001;Messelink *et al.*, 2005), substantial agreement of digital palpation was established between examiners in this current study. This current study's findings are in agreement with a number of others which indicate that when the appropriate statistical measures are used, and sufficient training and discussion given, (Jeyaseelan *et al.*, 2001;Devreese *et al.*, 2004;Frawley *et al.*, 2006b), significant agreement can be reached between examiners. Furthermore digital examination indicated that the voluntary activation of the PFM was significantly stronger in the continent compared to SUI group and differences between groups could also be established in the location of the contraction (Chapter 9). Digital palpation of voluntary PFM contraction was therefore more able to distinguish between continent and women with SUI than the displacement of the urethra or ARA measured during a voluntary PFM contraction using 2D ultrasound and IPM when the relative starting position of the pelvic tissue is unaccounted for.

Reliability has yet to be established for the novel intravaginal pressure probe, yet corrected measurements determined significant differences between the maximum active pressures generated during a PFM contraction between continent and SUI women (Chapter 12, Section 12.4.3). Furthermore, in the continent group, from a resting to a contracted state, there were statistically significant differences in corrected recorded pressures, whereas the pressures measured at rest and during a PFM contraction were not statistically different in the SUI group. As discussed earlier (Chapter 9, Chapter 15, Section 15.4) although there are continent women with weak PFM and SUI women with strong PFM, evidence based practice recommends strength training for rehabilitation of SUI, and this current study has indicated significant differences in both the strength and pressures of the PF in women with SUI (Chapter 9, 12).

15.5.3 Dynamic supportive function: stiffness, timing and direction of support:

The effect on the position of the pelvic organs due to a change in posture implies that the PF of the continent group is stiffer than that of SUI group, due to better connective tissue support and perhaps more effective PFM activity. Further evidence of increased stiffness and effective PFM activity was given when evaluating the effect of a cough, the Knack and Valsalva on the ARA and urethra (Chapters 6, 8 and 14 respectively). The displacement of the urethra and ARA was less in the continent group under comparable vaginal pressures and there was evidence of an automatic contraction of the PFM in continent women which was absent in women with SUI, indicated by the direction of displacement of the ARA.

The results of each study suggest that optimum PFM function is highly regulated to produce timely compression of the PF with additional external support to the urethra during events that increase IAP. The PFM shorten or stay the same length during a cough or Valsalva in supine, as indicated the reduction in distance between the ARA and SP and the initial direction of displacement. In SUI women, the muscle lengthens, indicated by the increase in distance between the ARA and SP. Consequentially this shortening, supportive contraction does not occur and the PF of SUI women is therefore more compliant than that of continent women. Subsequently the urethra and ARA are displaced further under comparable increases of vaginal pressure exposing the urethra and PF of SUI to Laplace-type forces associated with raised IAP.

However, as discussed earlier (Chapter 2, Section 2.9) EMG studies of the PFM have conflicting results, with some suggesting similar activation patterns in SUI compared to continent controls (Deindl *et al.*, 1994); some indicating delayed activation in SUI women (Constantinou & Govan, 1982;Barbic *et al.*, 2003;Deffieux *et al.*, 2007;Smith *et al.*, 2007a) and yet another indicating that women with incontinence demonstrating increased PFM EMG compared to continent women (Smith *et al.*, 2007b). These EMG studies once again highlight the difficulty in interpreting the electrical activity of a muscle, in terms of its magnitude or direction of force generation where the action of the muscle is not visible. Although EMG is a common measurement tool, electrode placement is of concern as there is evidence that different geographic areas within the PFM have different activity patterns, with some areas registering higher activity and others lower (Devreese *et al.*, 2004). Furthermore, EMG activity does not indicate how the muscle functions nor in which direction any force is generated. For example, when the ARA of the SUI group moves dorsal-caudal during a cough or Valsalva, the PFM will be elongated and may generate force eccentrically. As the PFM rebounds further and with greater acceleration and velocity in the SUI group, it provides another possible explanation to why the peak amplitude of EMG in SUI could be greater.

Our hypothesis of an automatic shortening contraction of the PFM in continent women was also supported by the comparison of urethral displacement values during a cough and Valsalva. Greater urethral displacements were recorded during a Valsalva compared to a cough in the continent group, whereas in the SUI group, the displacement values were similar (Chapter 13). As discussed earlier Howard et al (Howard *et al.*, 2000) and this current study reported similar displacement values of the BN during a cough and Valsalva manoeuvre, suggesting that the PFM had not responded to the increasing pressures generated during a cough. However the addition of a voluntary PFM contraction prior to and during a cough in SUI women was sufficient to reduce the displacement, velocity and acceleration of the urethra, to comparable values of a continent women coughing (The Knack, Chapter 8).

In continent women, not only is there evidence that in response to a cough and Valsalva there is automatic activation of the PFM (Chapter 6, 13), there is evidence of co-activation of the PFM muscles in response to a voluntary abdominal TrA contraction (Chapter 14). In women with SUI, there is also an automatic contraction of the PFM during a TrA contraction, although there is less ventral displacement of the ARA compared to continent women. Ventral displacement of urogenital structures produces compression of the urethra towards the SP, augmenting urethral closure pressure (DeLancey, 1988). IAP is generated by co-activation of the PFM, the diaphragm and the abdominal muscles (Hemborg *et al.*, 1985;Hodges & Gandevia, 2000). Muscles surrounding the abdominal cavity will therefore work together in a coordinated manner to increase IAP and support the pelvic organs (Hodges *et al.*, 2007). If the mechanisms of IAP generation and urethral closure pressure are both affected in SUI women, this could be another contributing mechanism by which the IAP exceeds urethral pressure facilitating leakage in incontinent women.

In addition to a stiffer PF to support the urethra, the fascial attachments of the urethra are thought to be stronger in continent women, any tear or break in the continuity of the fascia will limit the external support of the urethra, therefore contributing to greater displacement (DeLancey, 1994). As reported in Chapter 6, during a cough, the urethra of continent women is displaced less than half the distance with a smaller velocity than that of women with SUI. The combination of stronger urethral control due to intact fascia, and the presence of a PFM contraction in the continent group would account for the limitation of both the dorsal and caudal motion on the urethra during the cough and Valsalva. Furthermore, in this current study, the increased likelihood of fascial disturbances in the SUI group was illustrated by the fact that during a cough, the anterior edge of the urethra moved more than the posterior edge (Chapter 6, 7). In continent women, the anterior edge of the urethra, which has more direct fascial attachment to the SP than the posterior edge (Mostwin, 1991), moved less than the posterior edge.

Further evidence of an intact unit in the continent group was also observed during a cough (Chapter 7), Valsalva (Chapter 13) and also the correlation between ARA movement and urethral displacement during a voluntary PFM contraction (Chapter 11). In continent women, displacement of the ARA strongly correlates with displacement of the urethra, suggesting that the tissue moves together; whereas in women with SUI, the correlation was more moderate. In the SUI group, during a cough and Valsalva, there is greater change of angle between pelvic organ structures irrespective of posture, and the angles converge to the same degree, whereas the relative change in angle in continent women was constant regardless of posture. Our findings also suggest that the urethral deformation in the SUI group reached its elastic limit in supine and standing, most likely due to the combination of a lack of active and passive connective tissue restraints.

15.5.4 Implications for future PFM rehabilitation:

The results of the experimental chapters in this small group of women with SUI, suggest that for successful conservative rehabilitation of the PFM, four important qualities are required:

1. Automatic timing of a shortening contraction of the PFM during raises in IAP;
2. Increased stiffness and strength of the PF to better resist rises in IAP;
3. Appropriate positioning and support of the pelvic organs;
4. A PFM contraction that has the appropriate direction of displacement to support the urethra sufficiently to compensate for any fascial disturbances.

The latest Cochrane reviews of conservative rehabilitation of SUI provide evidence for the use of strengthening the PFM and the use of the Knack (Dumoulin & Hay-Smith, 2008). The author suggests that an important clinical and research challenge will be to determine how to restore the automatic timing function and direction of PFM contraction, sufficiently to compensate for any fascial disturbances. Although the Knack significantly reduces the displacement of the urethra during a cough and reduces the degree of incontinence (Miller *et al.*, 2001;Miller *et al.*, 2008); it is not known whether the normal timing function is ever restored. Furthermore, if the direction of the PFM contraction does not displace and support the urethra, it is the author's opinion that rehabilitation will be less successful.

Future research using this measurement tool possesses the potential to determine which parameters change following successful intervention, be it conservative, surgical or pharmaceutical, or indeed which parameters do not change when rehabilitation fails. For example, this study illustrates that forces external to the urethra are indeed important for continence function. One clinical and research challenge is then to continue to find how best to control these external factors and to use this knowledge to categorize patients with SUI into subgroups, potentially creating more efficient, appropriate intervention. For example, in the future, should we observe that normal PFM timing function is present; the forces external to the urethra are balanced; and observe that a patient with SUI has normal external support to the urethra; intervention could be directed towards the intrinsic urethral mechanisms. However, if the PFM do not produce timely compression of the urethra during a cough, intervention can be directed towards improving the function of the PFM.

15.6 Future studies

15.6.1 The reliability of the 2D TP imaging combined with IPM was established on stored audio-visual imaging (AVI) files as the aim was to establish the repeatability of the

IPM rather than the consistency of either the operator to capture the AVI files or the variability of the women repeating the manoeuvres. However it is acknowledged that repeating the entire examination at another date may result in lower repeatability indices and future clinical studies would allow these potential variances to be accounted for. Test re-test reliability of 2D TP ultrasound imaging combined with IPM would determine the variability associated with both the volunteer performing the manoeuvre, and the operator capturing the AVI file.

15.6.2 A case series intervention study to measure the effects of conservative rehabilitation of women with SUI using TP imaging combined with IPM. The results would then be used to determine sample size for a further randomised controlled trial, either using a control group with no intervention or comparing best current practice with intervention aimed at restoring the automatic timing function and direction of PFM contraction. The intra-tester, test-retest and ability of the Functional Scale to detect change with intervention could also be established in order to assess its potential as a clinically useful outcome measure.

15.6.3 As discussed earlier (Chapter 5, Section 5.5.2) there are methodological and technical improvements that could be made to the IPM in order to obtain enhanced information regarding the dynamic evaluation of the PFM. In particular, future studies should explore the possibility of an independent trigger to synchronise the beginning of a manoeuvre, such as IAP or EMG. Whichever method is chosen, preferably it should not artificially stiffen the PF. The measurement of concurrent IAP would also enable the cut-off pressure at which the PF is unable to resist the dorso-caudal displacement caused by increasing IAP. This study did also not quantitatively address the ability to fully relax the PFM, nor did it calculate the endurance of the PFM contraction, and it is suggested that both qualities of PFM function be incorporated into quantitative calculations.

15.6.4 As discussed earlier (Chapter 3, Section3.3 and Chapter 15, Section 15.3) parity status was significantly different between the two study groups. As 2D TP ultrasound combined with IPM has been shown to be reliable and feasible, further studies with larger populations of parity matched individuals would enhance the generalisability of the study findings.

15.6.5 2D TP imaging and IPM has the potential to dynamically evaluate the PF of other study groups with known PF dysfunctions, such as vaginal, rectal, and uterine prolapse and faecal incontinence. Furthermore, they could determine whether or not there is indeed PF dysfunction in other groups of patients, such as those with lumbar, sacral and pelvic pain. Future studies, involving any of these study populations, with appropriately matched control volunteers, could potentially uncover some of the physiological mechanisms of PFM dysfunction and monitor the effects of any treatment intervention.

15.6.6 2D TP imaging and IPM can reliably measure from ARA to pubic symphysis and ARA to urethra all the way during the cough, but we miss evaluation in the axial plane. Potentially using the 360 Transvaginal probe, if the frame rate is fast enough, could obtain these views and calculate hiatal area during a cough.

15.7 Summary

The discussion, limitations of this research and suggestions for further work have been presented with the aim of contextualising the findings as regards the meaning of this current research study and its continuity. The final chapter presents the main conclusions of this research.

16 Conclusions

16.1 Introduction

The overall aim of this research was to explore the potential for using 2D transperineal (TP) ultrasound combined with image processing methods (IPM) to extract novel information about the dynamic function of female Pelvic Floor Muscles (PFM). Its major strength was its ability to reliably visualise and quantify functional movements of the ano-rectal angle (ARA) and urethra throughout a whole manoeuvre rather than statically measure the displacement at rest to the end of the manoeuvre. It was able to quantify novel kinematics of PFM and urethral function such as the displacement velocity and acceleration during a cough and was sensitive enough to differentiate between manoeuvres and groups of continent and stress urinary incontinent (SUI) women. Significant differences were shown in the behaviour of the PFM and urethra of women with SUI, providing the opportunity of understanding further the structure and function of the PF, particularly related to the continence mechanism, how it functions and how it fails.

16.2 Conclusions

16.2.1 2D TP ultrasound combined with IPM was a reliable, valid method to describe and quantify the function of the PFM in women. It was specific and sensitive enough to distinguish between continent and SUI women. Future studies with larger parity matched populations are required before the generalisability of the results is warranted.

16.2.2 Two IPM, speckle tracking and segmentation were required to quantify the displacement of pelvic floor (PF) structures captured by 2D TP ultrasound. Both speckle tracking IPM and segmentation IPM had good to excellent statistical inter-observer reliability. Speckle tracking was less time intensive; however it was unable to track the urethra due to the degree of deformation that occurred during a cough. The reference point, the symphysis pubis (SP), from which displacements were measured, was not clear in each subject's film, therefore registration of the SP using the segmentation methodology, was impossible with current technology. Speckle tracking was therefore used to measure the apparent motion of the SP and the displacement of the ano-rectal angle (ARA); segmentation was used to measure the displacement of the urethra.

16.2.3 2D TP ultrasound combined with IPM was able to reliably determine the relative position of the ARA and urethra in supine and standing positions. The urethra and ARA of continent women were in a more cranio-ventral position in the pelvis than that of women with SUI, especially in a standing position. Studies describing displacement of PFM structures during manoeuvres in different positions need to account for the relative starting position, as although the displacement may appear greater (or smaller), the overall displacement will be affected by the initial starting position.

16.2.4 TP ultrasound combined with IPM was a valid measure of PFM function and the correlations between digital examination and ultrasound measurements were comparable for subgroups of continent and SUI women. Correlations with digital palpation scales of strength were moderate to good, suggesting that greater displacement of the PF is not an extremely sensitive measure of PFM strength. Caution is required when interpreting larger displacements as stronger PFM contractions or conversely smaller displacements representing poorer voluntary contractions of the PFM, particularly without access to a fixed reference point or accounting for the relative starting positions of PF structures. A larger displacement on ultrasound did not imply an anatomically higher final resting position of either the ARA or urethra.

16.2.5 Displacement of the ARA correlated highly with displacement of the urethra in continent women but more moderately in women with SUI.

16.2.6 The Functional Scale was a simple, reliable digital palpation scale that distinguished between continent women and women with SUI. It measured whether or not a voluntary PFM contraction caused a squeeze and inward lift of the PFM, with resultant urethral stabilization, and resistance to downward movement during a cough. The strength, displacement and function of the PFM differed between continent and SUI women and these differences could be reliably measured with digital palpation by examiners of different disciplines.

16.2.7 The Functional Scale was a valid digital measurement of PFM displacement which had good correlation with 2D TP ultrasound and IPM and appeared to account for differences in individual anatomy and muscle function. The intra-tester, test-retest and ability of the Functional Scale to detect change with intervention needs to be established in order to assess its potential as a clinically useful outcome measure.

16.2.8 Significant differences existed in the behaviour of the PFM and urethra of women with SUI compared with continent controls. Normal PFM function during a cough produced timely compression of the PF and additional external support to the urethra, reducing the velocity and acceleration of the PF and urethra. In response to a cough the PF and urethra of SUI women therefore moves further, faster and for longer than asymptomatic women. The restraining forces do not increase as rapidly with displacement as those in continent women; evidence that the urethra and PF of asymptomatic women is stiffer than that of continent women. In standing, the PF of women with SUI is exposed to tensile strain during a cough and provides an explanation of why women with SUI describe symptoms of leaking more frequently in standing compared to the supine position.

16.2.9 The PF of SUI women is more compliant than that of continent women, indicated by displacement values during a cough yet the addition of an active PFM contraction prior to and during a cough, “The Knack” is sufficient to reduce the displacement, velocity and acceleration of the urethra, to comparable values of a continent women coughing. 2D TP ultrasound combined with IPM is specific enough to distinguish between a cough without pre-contraction of the PFM and a cough with pre-contraction of the PFM. IPM therefore can inform us whether a woman is able to use their PFM effectively to displace and support the urethra during a cough and has highlighted the immediate potential benefits of the Knack as a rehabilitation tool.

16.2.10 During a Valsalva in supine there was evidence of an automatic contraction of the PFM in continent women which is absent in women with SUI. Further evidence that the PF of SUI women being more compliant than that of continent women.

16.2.11 There was an automatic activation of the PFM in response to a voluntary TrA contraction in both continent and SUI women. During a TrA contraction here was greater cranio-ventral displacement of the ARA in continent compared to women with SUI in supine and standing.

16.2.12 2D TP ultrasound combined with IPM is able to detect significant differences between the amount of displacement of the ARA and urethra in continent and SUI women when performing a voluntary PFM contraction in standing, although these differences are not significant in supine. The implication for future work is that during intervention studies, the standing position should be used in rehabilitation of women with SUI.

16.2.13 The novel vaginal pressure probe enabled the localisation and measurement of the pressure changes that occur in the vagina during a PFM contraction. The highest-closure forces occurred posteriorly located between the SP and UVJ and were predominately caused by the voluntary PFM contraction. Anteriorly, the profile curve was mainly influenced by the existence of the SP. Laterally there was a small incremental change registered by a PFM contraction. Vaginal pressures generated by a PFM contraction were significantly different between continent and SUI women.

Appendices

Appendix 1 Publications

Appendix 2: Testing Sequences

2a. Ultrasound Assessment **Position**	**Date** **Completed insert √**	**Patient Code** **comments**	**Data/movie file name**
BLADDER VOLUME			
Abdominal Ultrasound levator plate SUPINE			
Instructions to patients, all repeat x 3			
PFM Contraction 1. Slow MVC to count of 5 sec, release rest X 10 sec in-between contractions.			
Perineal Ultrasound Assessment SUPINE			
Instructions to patient, all repeat X 3 **Cough** 2. One hard cough, rest and breathe normally			
PFM Contraction 3. Slow MVC to count of 5 sec, release rest X 10 sec in-between contractions.			
Valsalva 4. Bear down to maximum, Rest x5 sec			
The Knack 5. PFM precontraction, hold whilst cough. Rest and breathe normally			
Transversus Abdominis (TrA) contraction 6. slow abdominal hollowing manoeuvre whilst breathing normally			
Abdominal Ultrasound Assessment above iliac crest 7. TrA contraction a/a 8. PFM contraction a/a **Perineal Ultrasound Assessment STANDING**			
Instructions to patient, all repeat X 3			
Cough			
9. One hard cough, rest and breathe normally			
PFM Contraction			
10. Slow MVC to count of 5 sec, release rest X 10 sec in-between contractions.			
Valsalva			
11. Breathe in breathe out as bear down to maximum,			
Rest x5 sec			
The Knack			
12. PFM precontraction, hold whilst cough. Rest and breathe normally			
Transversus Abdominis (TrA) contraction			
13. slow abdominal hollowing manoeuvre whilst breathing normally			

2b. Pelvic Floor Palpation (Ruth) **Position**	**Date**	**Patient Code**	
PERFECT ASSESSMENT (Protocol **Power: Oxford Scale**	Measurement (L) PFM	Measurement (R) PFM	Comment
0: Nil			
1: Flicker			
2: Weak			
3: Moderate			
4: Good			
5. Strong			
Endurance and Repetitions of Maximum Voluntary Contraction (MVC) (up to 5 contractions of maximal 10 seconds and 20 sec rest period)			
Endurance :Seconds			
Repetitions: Number			
Fast Contractions: number of fast contractions (max 10) 1 second MVC and relaxation			
a. **SUPERFICIAL PART OF PELVIC FLOOR (Protocol)**			
0: no contraction noticeable			
1: flicker of contraction			
2: inward displacement and obvious squeeze around proximal part of the testing finger			
3: inward displacement and strong squeeze around proximal part of testing finger			
b. **DEEP PART OF PELVIC FLOOR (protocol)**			
0: no contraction noticeable			
1: flicker of contraction			
2: inward displacement of the distal part of the testing finger without total extension			
3: inward displacement of the distal part of the testing finger with total extension			
4: inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient without contact with the cranial part of the vagina			
5: Inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient. The pelvic floor muscle tightens around the finger **SYMMETRY OF CONTRACTION**			
0. Asymmetrical: When comparing the superficial PFM to the deep PFM there is asymmetry of PFM contraction			
1.Symmetrical: When comparing superficial PFM to deep PFM There is overall symmetry of PFM contraction as described by an even displacement & lift of the distal and proximal part of the finger			
0. Asymmetrical: when comparing the (R) PFM to the (L) PFM there is asymmetry of PFM contraction			
1. Symmetrical: When comparing the (R) PFM to the (L) PFM there is overall symmetry of PFM contraction			
0. Breathing Pattern: does change throughout manouevre			
1. Breathing Pattern: does not change throughout manouevre			

Appendix

ORIGINAL PROTOCOL RUTH JONES

Protocol Ruth Jones **FUNCTIONAL ASSESSMENT OF THE PELVIC FLOOR MUSCLES** **(displacement/stiffness of urethro-vesical junction (UVJ) on active PFM contraction)**			Comments
0. Absent: not present			
1. Poor: present in minor degree able to feel sensation on one aspect of palpating finger			
2. Fair: able to feel sensation on two aspects of palpating finger			
3. Good: obvious sensation of displacement on all aspects of palpating finger			
4. Functional: able to maintain displacement on cough			
5. Reflex: unable to feel displacement on all aspects on active PFM contraction, although can feel sensation on cough.			
0. Breathing Pattern: does change throughout manoeuvre			
1. Breathing Pattern: does not change throughout manoeuvre			
FUNCTIONAL ASSESSMENT OF TRANSVERSUS ABDOMINIS (TrA) **(displacement of UVJ on active TrA contraction)**			
0.Absent: not present			
1.Poor: present in minor degree able to feel sensation on one aspect of palpating finger			
2. Fair: able to feel sensation on two aspects of palpating finger			
3. Good: obvious sensation of displacement on all aspects of palpating finger			
4. Functional: able to maintain displacement on cough			
0. Breathing Pattern: does change throughout manoeuvre			
1. Breathing Pattern: does not change throughout manoeuvre			
CO-ACTIVATION OF PFM PALPATED VAGINALLY WITH VOLUNTARY TrA CONTRACTION **0. Absent:** not present			
1.Unilateral (L): There is unilateral (L) sided co-activation of PFM			
1.Unilateral (R): There is unilateral (R) sided co-activation of PFM			
2.Bilateral Co activation: There is bilateral co-activation of PFM			
0. Breathing Pattern: does change throughout manoeuvre			
1. Breathing Pattern: does not change throughout manoeuvre			
CO-ACTIVATION OF TrA PALPATED ABDOMINALLY WITH VOLUNTARY PFM CONTRACTION **0. Absent:** not present			
1.Unilateral (L):There is unilateral (L) sided co-activation of TrA			
1.Unilateral (R):There is unilateral (R) sided co-activation of TrA			
2.Bilateral Coactivation:There is bilateral co-activation of TrA			
0. Breathing Pattern: does change throughout manoeuvre			
1. Breathing Pattern: does not change throughout manoeuvre			

2c. Pelvic Floor Palpation (Chris Pagne) **Position**	**Date**	**Patient Code**	
PERFECT ASSESSMENT (Protocol Jo Laycock) **Power: Oxford Scale**	Measurement (L) PFM	Measurement (R) PFM	Comment
0: Nil			
1: Flicker			
2: Weak			
3: Moderate			
4: Good			
5. Strong			
Endurance and Repetitions of Maximum Voluntary Contraction (MVC) (up to 5 contractions of maximal 10 seconds and 20 sec rest period)			
Endurance: Seconds			
Repetitions: Number			
a. **SUPERFICIAL PART OF PELVIC FLOOR**			
0: no contraction noticeable			
1: flicker of contraction			
2: inward displacement and obvious squeeze around proximal part of the testing finger			
3: inward displacement and strong squeeze around proximal part of testing finger			
b. **DEEP PART OF PELVIC FLOOR**			
0: no contraction noticeable			
1: flicker of contraction			
2: inward displacement of the distal part of the testing finger without total extension			
3: inward displacement of the distal part of the testing finger with total extension			
4: inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient without contact with the cranial part of the vagina			
5: Inward displacement of the distal part of the testing finger with total extension. While in extension, finger provides resistance to caudal part of vagina which can be resisted by patient. The pelvic floor muscle tightens around the finger **SYMMETRY OF CONTRACTION**			
0. Asymmetrical: When comparing the Superficial PFM to the Deep PFM there is asymmetry of PFM contraction			
1.Symmetrical: When comparing Superficial PFM to Deep PFM There is overall symmetry of PFM contraction as described by an even displacement & lift of the distal and proximal part of the finger			
0. Asymmetrical: when comparing the (R) PFM to the (L) PFM there is asymmetry of PFM contraction			
1. Symmetrical: When comparing the (R) PFM to the (L) PFM there is overall symmetry of PFM contraction			

FUNCTIONAL ASSESSMENT OF THE PELVIC FLOOR MUSCLES (displacement/stiffness of urethro-vesical junction (UVJ) on active PFM contraction)			
0. Absent: not present			
1. Poor: present in minor degree able to feel sensation on one aspect of palpating finger			
2. Fair: able to feel sensation on two aspects of palpating finger			
3. Good: obvious sensation of displacement on all aspects of palpating finger			
4. Functional: able to maintain displacement on cough			
5. Reflex: unable to feel displacement on all aspects on active PFM contraction, although can feel sensation on cough.			
Assessment by Speculum			

TEST Nº	2d. PF Probe Testing Sequence 4	Date	Volunteer Code
	SUPINE Position		
	PROBE ADJUSED TO MAX DIAMETER SETTING turned 45 degrees and with dynamic measurements, positioned at position of max force recorded on profile test 1		
1	PROFILE VAGINA sub-maximal PFM contraction		
2	COUGH , relax, Repeat X3		
3	Slow PFMC , relax, Repeat X3		
4	VALSALVA, relax repeat X 3		
5	KNACK, relax, Repeat X3		
6	Transversus Abdominis (TrA) contraction		
7	PROFILE VAGINA no contraction		
	STANDING POSITION		
	PROBE ADJUSED TO MAX DIAMETER SETTING turned 45 degrees and with dynamic measurements, positioned at position of max force recorded on profile test 7		
8	PROFILE VAGINA sub-maximal PFM contraction		
9	COUGH , relax, Repeat X3		
10	Slow PFMC , relax, Repeat X3		
11	VALSALVA, relax repeat X 3		
12	KNACK, relax, Repeat X3		
13	Transversus Abdominis (TrA) contraction		
14	PROFILE VAGINA no contraction		

Appendix 3
Demographic Questionnaire (DQ)

Date of Testing:

<table>
<tr><td>Name:

DOB: Age:

Height:

Weight:

Ethnic Group:</td><td>Address:</td><td>Telephone:

H:

W:

Cell:

Email:</td></tr>
<tr><td>Number of children

Weight Heaviest Baby

Pregnant now Y/N</td><td>Types of Delivery and dates</td><td>Your Occupation & Hobbies:</td></tr>
<tr><td>Medical History:
Answer Y/N and add any further relevant information below

Cystitis:
Smoking:
Respiratory Problems:
Allergies:
Cardiac Problems:</td><td>Medical History continued:

Back problems:

Neck Problems:

Diabetes:

Current medication:</td><td>Surgical History</td></tr>
<tr><td>Menopausal State

Pre
Peri
Post
Hormone Replacement Therapy (HRT) Y/N
date commenced</td><td colspan="2">Any other information you think may be relevant and wish to tell us</td></tr>
</table>

Appendix 4

4a. Short form Incontinence Impact Questionnaire (IIQ-7)

Some women find that accidental urine loss and/or prolapse may affect their activities, relationships, and feelings. The questions below refer to areas in your life which may have been influenced or changed by your problem. For each question, check the response that best describes how much your activities, relationships, and feelings are being affected by urine leakage and/or prolapse.

I. Has urine leakage and/or prolapse affected your:
A. Ability to do household chores (cooking, housecleaning, laundry)?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

E. Physical recreational activities such as walking, swimming, or other exercise?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

F. Entertainment activities such as going to a movie or concert?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

H. Ability to travel by car or bus more than 30 minutes from home?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

O. Participating in social activities outside your home?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

T. Emotional health (nervousness, depression, etc.)?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

In addition, does your problem cause you to experience any of the following feelings?
AA. Frustration

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

Appendix

In addition to IIQ-7, the following questions (M, P, R and W) have been added:
I. Has urine leakage and/or prolapse affected your:
M. Employment (work) outside the home?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

P. Relationship with friends?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

R. Ability to have sexual relations?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

W. Does fear of odor restrict your activities?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

4b. Short form Urogenital Distress Inventory (UDI-6)

The next set of questions deals specifically with your accidental urine loss and/or prolapse.

I. The following symptoms have been described by women who experience accidental urine loss and/or prolapse. Please indicate which symptoms you are now experiencing, and how bothersome they are for you. Be sure to answer all items.

A. Do you experience frequent urination?

Yes	No (Skip to C.)
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

C. Do you experience urine leakage related to the feeling of urgency?

Yes	No (Skip to D.)
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

D. Do you experience urine leakage related to physical activity, coughing or sneezing?

Yes	No (Skip to F.)
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

F. Do you experience small amounts of urine leakage (that is, drops)?

Yes	No (Skip to J.)
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

J. Do you experience difficulty emptying your bladder?

Yes	No (Skip to N.)
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

N. Do you experience pain or discomfort in the lower abdominal or genital area?

Yes	No
☐	☐

If yes, how much does it bother you?

Not at all	Slightly	Moderately	Greatly
☐	☐	☐	☐

Appendix 5

5a. Motion tracking algorithms

Initially, a template of the SP is manually defined in the first frame of the ultrasound video. The template is then compared with the second image frame with different offsets in both x and y direction. The matched position in the second image frame is defined as the position where the difference function $D(k,l)$, given by Eqn. (1), has the minimum value. The function of difference $D(k,l)$ is defined as:

$$D(k,l) = \sum_{i=0}^{M-1}\sum_{j=0}^{N-1}\left|T_{i,j} - P_{i+k,j+l}\right| \qquad (1)$$

where, $T_{i,j}$ and $P_{i+k,j+l}$ are the template and the image to be matched respectively. M and N is the size of the template. k and l are offsets for matching at different position.

The template for the matching the following image frames is then updated according to Eqn. (2) and the matching procedure is repeated until the last image frame.

$$T(n) = \frac{1}{n}\sum_{i=0}^{n-1} S(i) = \frac{n-1}{n}T(n-1) + \frac{1}{n}S(n-1) \qquad n \geq 2 \qquad (2)$$

where, $S(i)$ is the matched position of the SP in image frame i.

A similar adaptive matching algorithm is developed to track the motion of ARA. However, ARA is a soft tissue structure which deforms, particularly in fast manoeuvres like coughing. Therefore, a weight coefficient is introduced to speed up the updating of the template in order to follow the deformations:

$$T(n) = w \cdot T(n-1) + (1-w) \cdot S(n-1) \qquad n \geq 2 \qquad (3)$$

where, w is the weight coefficient, $w \in [0,1]$. In practice, w is set to a value between 0.7 and 0.8 according to the extent of the ARA deformation. To decrease the effect of the size and position of the initial template, manually defined in the first image frame, the tracking procedure is performed four times with different initial templates and the results are averaged. The relative movement of ARA to the SP is then derived by subtracting the motion of SP from that of ARA.

5b. Comparison of the movement of pubis bone measured by FOB and by ultrasound

A global coordinate system (x-y-z) is fixed on the transmitter. During the experiment, the operator found the appropriate position with the best ultrasound image at first. A local coordinate system (*x*'-*y*'-*z*') fixed on that position was established to compare the movement measured by the ultrasound.

O and *O*' are the origin points of the global (transmitter) and the local coordinate systems respectively. The FOB measured the coordinate of the point *O*' (x_0, y_0, z_0) and the orientation of the bird (θ_a, θ_e, θ_r; namely, azimuth, elevation and roll angles) on the global coordinate system.

The relationship between the global (*x*-*y*-*z*) and the local (*x*'-*y*'-*z*') coordinate system is

$$\begin{bmatrix} x \\ y \\ z \end{bmatrix} = M \cdot \begin{bmatrix} x' \\ y' \\ z' \end{bmatrix} + \begin{bmatrix} x_0 \\ y_0 \\ z_0 \end{bmatrix} \tag{1}$$

where, ***M*** is rotation matrix:

$$M = \begin{bmatrix} \cos\theta_e \cos\theta_a & \cos\theta_e \sin\theta_a & -\sin\theta_e \\ \sin\theta_r \sin\theta_e \cos\theta_a - \cos\theta_r \sin\theta_a & \sin\theta_r \sin\theta_e \sin\theta_a + \cos\theta_r \cos\theta_a & \sin\theta_r \cos\theta_e \\ \cos\theta_r \sin\theta_e \cos\theta_a + \sin\theta_r \sin\theta_a & \cos\theta_r \sin\theta_e \sin\theta_a - \sin\theta_r \cos\theta_a & \cos\theta_r \cos\theta_e \end{bmatrix} \tag{2}$$

where, θ_a, θ_e, and θ_r are azimuth, elevation and roll angles in Euler angle notation.

The movement of the bird to the transmitter (the global coordinate system) was recorded. Therefore, the movement of the bird to the local coordinate system is

$$\cdot \begin{bmatrix} x' \\ y' \\ z' \end{bmatrix} = M^{-1} \cdot \begin{bmatrix} x - x_0 \\ y - y_0 \\ z - z_0 \end{bmatrix} \tag{3}$$

where, ***M***$^{-1}$ is the inverse of the matrix ***M***.

5c. Segmentation algorithms

The function of the posterior inferior margin of the symphysis pubis in the coordinate system of the image (x-o-y) is shown as

$$\frac{(x\cos\theta + y\sin\theta - x_c)^2}{a^2} + \frac{(-x\sin\theta + y\cos\theta - y_c)^2}{b^2} = 1$$

(1)

where a and b are the length of major and minor axis of ellipse respectively. xc and yc are the translations of the centre of the ellipse in x and y direction. θ is the rotational angle. Equation 1 can be transformed to:

$$a_0 x^2 + a_1 xy + a_2 y^2 + a_3 x + a_4 y = 1$$

(2)

where,

$$\begin{cases} a_0 = \left(\dfrac{\cos^2\theta}{a^2} + \dfrac{\sin^2\theta}{b^2}\right) \Big/ \left(1 - \dfrac{x_c^2}{a^2} - \dfrac{y_c^2}{b^2}\right) \\ a_1 = \left(\dfrac{\sin 2\theta}{a^2} - \dfrac{\sin 2\theta}{b^2}\right) \Big/ \left(1 - \dfrac{x_c^2}{a^2} - \dfrac{y_c^2}{b^2}\right) \\ a_2 = \left(\dfrac{\sin^2\theta}{a^2} + \dfrac{\cos^2\theta}{b^2}\right) \Big/ \left(1 - \dfrac{x_c^2}{a^2} - \dfrac{y_c^2}{b^2}\right) \\ a_3 = \left(-\dfrac{2x_0\cos\theta}{a^2} + \dfrac{2y_0\sin\theta}{b^2}\right) \Big/ \left(1 - \dfrac{x_c^2}{a^2} - \dfrac{y_c^2}{b^2}\right) \\ a_4 = \left(-\dfrac{2x_0\sin\theta}{a^2} - \dfrac{2y_0\cos\theta}{b^2}\right) \Big/ \left(1 - \dfrac{x_c^2}{a^2} - \dfrac{y_c^2}{b^2}\right) \end{cases}$$

(3)

Coefficients $a_0 \sim a_4$ are then estimated using Least Squares Estimation (LSE):

$$A = (X'X)^{-1} X'Y$$

(4)

where, A is a 5-by-1 vector of coefficients,

$$A = \begin{bmatrix} a_0 \\ a_1 \\ \vdots \\ a_5 \end{bmatrix}$$

(5)

X is an n-by-5 matrix,

$$X = \begin{bmatrix} x_0^2 & x_0 y_0 & y_0^2 & x_0 & y_0 \\ x_1^2 & x_1 y_1 & y_1^2 & x_1 & x_1 \\ \vdots & \vdots & \vdots & \vdots & \vdots \\ x_{n-1}^2 & x_{n-1} y_{n-1} & y_{n-1}^2 & x_{n-1} & x_{n-1} \end{bmatrix}$$

(6)

where, (x_0, y_0), (x_1, y_1), $\cdots, (x_{n-1}, y_{n-1})$ are the coordinate of the points on the posterior inferior margin of the symphysis pubis acquired by the automatic segmentation in a single frame. n: is number of the points.

Y is an n-by-1 vector of ones,

$$Y = \begin{bmatrix} 1 \\ 1 \\ \vdots \\ 1 \end{bmatrix}$$

(7)

Then the parameters a, b, θ, x_c, y_c were calculated from equation 3. It is reasonable to assume the symphysis pubis is a rigid body and the parameters a, b do not change when the symphysis pubis moves. The final estimations, therefore of parameters a, b were then calculated by averaging the parameters a, b of all frames in the movie. Moving averaging filtering was performed to eliminate the noise in the parameters θ, x_c, y_c. The spans of the moving averages of the cough data, the contraction data and the Valsalva data are set as 2, 24 and 100 respectively, according to the different speed of cough, contraction and Valsalva.

The point (x', y') in the coordinate system fixed on the posterior inferior margin of the symphysis pubis were then calculated by,

$$\begin{cases} x' = x\cos(-\theta) - y\sin(-\theta) - x_c - a \\ y' = x\sin(-\theta) + y\cos(-\theta) - y_c \end{cases}$$

(8)

where, (x, y) is the coordinate in the coordinate system of the image.

To describe the differences qualitatively, the directions of the movement of the three positions were derived by linear regression,

$$y' = kx' + b$$

(9)

where, k is the slope. b is the intercept.

The original 16bit intensity images with integer values in the range [0, 65535] were converted to binary images with logical value of 0s (black) and 1s (white). Otsu's method (Otsu & Threshold, 1979), that minimizes the intra-class variance of the black and white pixels, was used to determine the threshold for the conversion. All pixels in the intensity image with value less than the threshold have value 0 (black) in the binary image. In addition, all other pixels have value 1 (white) in the binary image. Then the isolated pixels (individual 1's that are surrounded by 0's) were removed from the binary images.

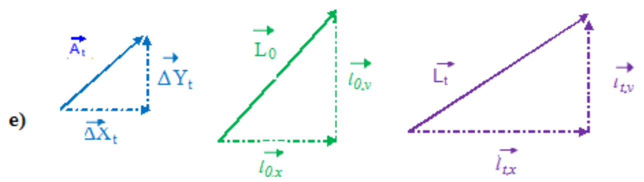
5d Strain calculations:

From the displacement measurements, muscle strain ε was calculated.

$\varepsilon = \frac{\| \vec{L}_t \| - \| \vec{L}_0 \|}{\| \vec{L}_0 \|}$,**(1)** $\| \vec{L}_0 \|$ and $\| \vec{L}_t \|$ represents the length at rest and length at time *t* respectively and is $\| \vec{L}_t \| = \sqrt{\left(\vec{l}_{t,x}\right)^2 + \left(\vec{l}_{t,y}\right)^2}$ **(2)** $\vec{l}_{t,x}$ representing the dorsal-ventral component of the PFM at time t and is measured by the equation $\vec{l}_{t,x} = \Delta\vec{x}\,t + \vec{l}_{0,x}$ **(3)** and $\vec{l}_{t,y}$ is the vector representing cranio-caudal component of the muscle at time t and is defined by the equation $\vec{l}_{t,y} = \Delta\vec{y}\,t + \vec{l}_{0,y}$ **(4),** $\vec{l}_{0,x}$ and $\vec{l}_{0,y}$ are the dorsal-ventral and cardinal-caudal vector components of the muscle at rest (t=0) respectively. $\Delta\vec{x}$ t and $\Delta\vec{y}$ t are the dorsal-ventral and cardinal-caudal displacements, respectively at time t. In order to calculate strain from **(2**), the $\Delta\vec{x}_t$ and $\Delta\vec{y}_t$ values from the displacement graphs were extracted using xy Extract (V 2.5). Then the values of the two displacement components were matched to same time values with the matching criteria of the measurements being within ± 0.005 seconds of each other. Thus the mean of time measurements was calculated and **(3)** and **(4)** and subsequently **(2)** was applied to calculate **(1)** for all the collected data points. Subsequently strain vs. time was graphed for the two groups and the maximum strain was calculated and compared for significant differences.

Strain Rate (SR) is the time derivative of $\ln \frac{L}{L_0}$ and $\frac{dL}{L} \approx \frac{v\,(r + \Delta r) - v(r)}{\Delta r} dt = SR\ dt$ **(5)** (Gilja et al 2002) *r* represents the position of the point on the ARA, thus $\Delta r = \| \vec{L}_t \|$, defined by **(2),** vector notation is given below.

Appendix



PFM is simplified as a straight line from SP to ARA.

(a);Vectors $\vec{L}_t$ (purple at time t), $\vec{L}_0$ (green at rest), and $\vec{A}_t$ (blue vector representing the resultant vector of the displacement vectors $\Delta\vec{x}_t$, $\Delta\vec{y}_t$ at time *t*.

Hence, $v(r+\Delta r) - v(r) = \Delta v = \sqrt{(\Delta v_x)^2 + (\Delta v_y)^2}$ **(6)**

SR is related to ε from $\varepsilon = \exp(\int_{t_0}^{t} SR\,dt) - 1$ **(7)**

From **(5),** the SR was calculated using the algorithm of picking points from the graph using xy Extract and the matching algorithm described for strain measurement, with the addition that now the time measurement needed to be matched for both velocity and displacement in dorsal-ventral and cardinal-caudal direction. Thus, the mean time value was calculated by averaging the four matched values, and the similar method described in the strain measurement using Microsoft Excel was used to apply **(6)** to all the collected data points. Subsequently strain rate vs. time was graphed for the two groups and the maximum strain rate was calculated and compared for significant differences.

5. Probe Calculations

Contact pressure *P,* derived from the contact area (*S*) and the force along the vaginal walls (*F*) is given by P=F/S where the diameter of the force sensor was 0.54cm. Contact pressure, expressed in N/cm^2 is given by $P = 0.0428 \cdot F$. Calibration of force sensors was done using an electronic balance, with the data interpolated using a fourth-order polynomial equation.

5. 1: Changes of the pressure in four directions by PFM contraction

To evaluate the pressure produced by a PFM contraction, we estimated the changes of the pressure in four directions as follows:

Assuming that insertion of the palpation probe will deform the vaginal wall, the resting pressure P_{rest} measured by the palpation probe is defined as:

$$P_{rest} = P_{residual} + P_{stretch} \quad (5)$$

where $P_{residual}$ is the vaginal closure pressure (residual stress) without the probe. $P_{stretch}$ is the pressure produced by the deformation of the vagina.

With PFM contraction, for example, the pressure $P_{PFM\,(posterior)}$ measured by the force sensor on the posterior side of the palpation probe is:

$$P_{PFM\,(posterior)} = P_{residual(posterior)} + P_{stretch(posterior)} + P_{PFM} \quad (6)$$

where P_{PFM} is the pressure in the posterior direction produced by the PFM contraction.

Therefore, the pressure P_{PFM} produced by the PFM contraction can be derived by subtracting the resting pressure $P_{rest(posterior)}$ from the pressure $P_{PFM\,(posterior)}$ ("(posterior)" in the subscript means pressure measured by the sensor on the posterior side of the palpation probe):

$$P_{PFM} = P_{PFM\,(posterior)} - P_{rest(posterior)} \quad (7)$$

Influence of PFM contraction

Increments of pressure generated by PFM contraction were detected in both the anterior and posterior directions. To investigate the influence of a PFM contraction, the differences between the pressures on the posterior and anterior vaginal walls were estimated as follows.

When the vagina is stretched by the probe, the difference between the pressures measured by the posterior sensor and anterior sensor on the vaginal palpation probe ($P_{probe(p-a)}$) is:

$$P_{probe(p-a)} = (P_{residual(posterior)} + P_{stretch(posterior)} + P_{activity(posterior)}) - (P_{residual(anterior)} + P_{stretch(anterior)} + P_{activity(anterior)}) \quad (8)$$

where, $P_{activity(anterior)}$ and $P_{activity(posterior)}$ are the pressures produced by the forces of the pelvic floor (PFM contraction, increased abdominal pressure etc.).

When there is no probe, the vagina stays in an equilibrium state. Therefore, the vaginal closure pressures (residual stress) are the same on the anterior and posterior vaginal wall, namely:

$$P_{residual(posterior)} = P_{residual(anterior)} \quad (9)$$

Due to the flexibility of the vaginal wall, the pressures produced by a small deformation of vagina are negligible when measuring VPP during maneuvers such as PFM contraction and Valsalva. Therefore, $P_{probe(p-a)}$ is:

$$P_{probe(p-a)} \approx P_{activity(posterior)} - P_{activity(anterior)} = P_{activity(p-a)} \quad (10)$$

Equation 10 implies that the difference of the pressures produced on the posterior side and anterior side of the vaginal walls ($P_{activity(p-a)}$) is approximately equal to the difference between the pressures measured by the posterior sensor and anterior sensor on the vaginal palpation probe ($P_{probe(p-a)}$). Higher $P_{activity(p-a)}$ will produce more deformation in the vagina and urethra which may result in increasing closure pressure in the urethra.

Visualization of vaginal closure pressures

By applying the linear interpolation on all the pressure measurements along the vaginal wall, the two-dimensional distribution of the pressures of the vaginal walls can then be approximately derived.

As shown in Figure 2, the contact pressures around the probe can be approximately derived from those measured in the anterior, left, posterior and right directions using linear interpolation. For example, the pressure P_q on position "Q" is:

Appendix

$$P_q = \frac{\theta_l}{\pi/2} P_a + \frac{\theta_a}{\pi/2} P_l \tag{11}$$

where, P_a and P_l are the pressures in the anterior and left directions respectively. The definitions of angle θ_a and θ_l are shown in Figure 2.

The contact pressures in other three quadrants (anterior-right quadrant, right-posterior quadrant and posterior-left quadrant) can be calculated similarly.

Appendix 6

Timeline PhD Ruth Lovegrove (RL)

October 2003- August 2004: Registered part time DClinP School Nursing & Midwifery Southampton University. Attending Statistical / taught courses. Refining research question regarding Pelvic Floor Muscle (PFM) function, decide to primarily evaluate using ultrasound. Start forming research proposal.
August 2004- April 2005: Invited to Stanford University to join team (Dr C Constantinou (CC) Dr Qiyu Peng QP) which was currently evaluating PFM function using intra-vaginal probe. Develop assessment protocols (RL+ QP +CC) and start to develop image processing methods (IPM) on previously captured audio video (AVI) files (RL + QP). Apply for ethical approval from Stanford University to add ultrasound evaluation to current study trial (CC+ RL).
April 2005- June 2005: Transfer registration to PhD at School Health Professions, Southampton University, UK and primary supervisors Prof Maria Stokes (MS) & Victor Humphrey (VH). Agreement reached between universities to allow collection of data to be used for PhD in UK. Move to Stanford University, Ethical Approval granted. MS and VH assist in supervisory role from UK, assist with evaluation/validity/interpretation of IPM ultrasound and study protocols highlighted below.
July- August 2005: Commence recruitment of study volunteers (RL + Tina Allee). Collect ultrasound, palpation and probe data (RL physically collecting all data from volunteers, QP capturing all associated computer data from probe, ultrasound, Chris Payne (CP) some vaginal palpation data for reliability.
August 2005- July 2006. Developing and refining ultrasound software programmes for AVI files (QP + RL). Analysis preliminary results on cough (RL+QP +CC + supervisors). Examined reliability of IPM measures (RL +QP+ supervisors). Started image processing of ultrasound data analysis on other manoeuvres (QP+RL+KS.
July 2006-April 2007: Write and defend MPhil Transfer thesis. Continue and complete ultrasound data analysis (QP+RL).
April 2007-Sept 2008: Discover error in ultrasound data analysis (RL). Redo ultrasound programming (QP) new data analysis and interpretation of results (RL). Complete palpation, probe analysis (RL). Start writing up PhD thesis.
September 2008- July 2009: Return to Southampton, UK. Continue with data analysis and interpretation of results (RL). Complete PhD thesis.
December 2009: thesis defence.
Key
RL = Ruth Lovegrove, QP = Qiyu Peng, CC + Christos Constantinou, CP = Chris Pagne, TA = Tina Allee, KS = Keiichi Shishedo

Reference List

Abdel-fattah M, Barrington JW, & Youssef M (2004). The standard 1-hour pad test: does it have any value in clinical practice? *European Urology* **46**, 377-380.

Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, Van KP, Victor A, & Wein A (2002). The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *American Journal of Obstetrics & Gynecology* **187**, 116-126.

Allen RE, Hosker GL, Smith AR, & Warrell DW (1990). Pelvic floor damage and childbirth: a neurophysiological study.[see comment]. *British Journal of Obstetrics & Gynaecology* **97**, 770-779.

Alper T, Cetinkaya M, Okutgen S, Kokcu A, & Malatyalioglu E (2001). Evaluation of urethrovesical angle by ultrasound in women with and without urinary stress incontinence. *International Urogynecology Journal* **12**, 308-311.

Amarenco G, Ismael SS, Lagauche D, Raibaut P, Rene-Corail P, Wolff N, Thoumie P, & Haab F (2005). Cough anal reflex: strict relationship between intravesical pressure and pelvic floor muscle electromyographic activity during cough. Urodynamic and electrophysiological study.[see comment]. *Journal of Urology* **173**, 149-152.

Armstrong SM, Miller JM, Benson K, Jain S, Panagopoulos K, DeLancey JO, & Sampselle CM (2006). Revisiting reliability of quantified perineal ultrasound: Bland and Altman analysis of a new protocol for the rectangular coordinate method. *Neurourology & Urodynamics* **25**, 731-738.

Ashton-Miller JA & DeLancey JOL (2007). Functional anatomy of the female pelvic floor. *Reproductive BiomechanicsAnnals of the New York Academy of Sciences* **1101**, -296.

Ashton-Miller JA, Howard D, & DeLancey JOL (2001). The functional anatomy of the female pelvic floor and stress continence control system. *Scandinavian Journal of Urology and Nephrology, Supplement* **35**, 1-7.

Ashton-miller J & Delancey JOL (2007). Functional Anatomy of the Female Pelvic Floor. *Ann NY Acad Sci* **1101**, 266-296.

Ashworth PD & Hagan MT (1993). The meaning of incontinence: a qualitative study of non-geriatric urinary incontinence sufferers. *Journal of Advanced Nursing* **18**, 1415-1423.

References

Athanasiou S, Chaliha C, Toozs-Hobson P, Salvatore S, Khullar V, & Cardozo L (2007). Direct imaging of the pelvic floor muscles using two-dimensional ultrasound: A comparison of women with urogenital prolapse versus controls. *BJOG: An International Journal of Obstetrics and Gynaecology* **114**, 882-888.

Athanasiou S, Khullar V, Boos K, Salvatore S, & Cardozo L (1999). Imaging the urethral sphincter with three-dimensional ultrasound. *Obstetrics & Gynecology* **94**, 295-301.

Bai SW, Lee JW, Shin JS, Park JH, Kim SK, & Park KH (2004). The predictive values of various parameters in the diagnosis of stress urinary incontinence. *Yonsei Medical Journal* **45**, 287-292.

Barbic M, Kralj B, & Cor A (2003). Compliance of the bladder neck supporting structures: importance of activity pattern of levator ani muscle and content of elastic fibers of endopelvic fascia. *Neurourology & Urodynamics* **22**, 269-276.

Baytur YB, Deveci A, Uyar Y, Ozcakir HT, Kizilkaya S, & Caglar H (2005). Mode of delivery and pelvic floor muscle strength and sexual function after childbirth. *International Journal of Gynaecology & Obstetrics 88(3):276-80*.

Beco J, Leonard D, & Lambotte R (1994). Study of the artefacts induced by linear array transvaginal ultrasound scanning in urodynamics. *World Journal of Urology* **12**, 329-332.

Beer-Gabel M, Teshler M, Barzilai N, Lurie Y, Malnick S, Bass D, & Zbar A (2002). Dynamic transperineal ultrasound in the diagnosis of pelvic floor disorders: pilot study. *Diseases of the Colon & Rectum* **45**, 239-245.

Benacerraf BR, Benson CB, Abuhamad AZ, Copel JA, Abramowicz JS, Devore GR, Doubilet PM, Lee W, Lev-Toaff AS, Merz E, Nelson TR, O'Neill MJ, Parsons AK, Platt LD, Pretorius DH, & Timor-Tritsch IE (2005). Three- and 4-dimensional ultrasound in obstetrics and gynecology: proceedings of the american institute of ultrasound in medicine consensus conference. [83 refs]. *Journal of Ultrasound in Medicine* **24**, 1587-1597.

Benvenuti F, Caputo GM, Bandinelli S, Mayer F, Biagini C, & Sommavilla A (1987). Reeducative treatment of female genuine stress incontinence. *American Journal of Physical Medicine* **66**, 155-168.

Berghmans LC, Hendriks HJ, Bo K, Hay-Smith EJ, de Bie RA, & van Waalwijk van Doorn ES (1998). Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. *British Journal of Urology* **82**, 181-191.

References

Bernstein I, Juul N, Gronvall S, Bonde B, & Klarskov P (1991). Pelvic floor muscle thickness measured by perineal ultrasonography. *Scandinavian Journal of Urology & Nephrology Supplementum* **137**, 131-133.

Bernstein IT (1997). The pelvic floor muscles: muscle thickness in healthy and urinary-incontinent women measured by perineal ultrasonography with reference to the effect of pelvic floor training. Estrogen receptor studies. [Review] [145 refs]. *Neurourology & Urodynamics* **16**, 237-275.

Bland JM (1987). Clinical measurement. In *An introduction to medical statistics*, ed. Bland JM, pp. 265-273. Oxford University Press.

Bland JM & Altman DG (1986). Statistical methods for assessing agreement between two methods of clinical measurement.[see comment]. *Lancet* **1**, 307-310.

Bland JM & Altman DG (1990). A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. *Computers in Biology & Medicine* **20**, 337-340.

Bo K (2004). Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work?. [Review] [68 refs]. *International Urogynecology Journal* **15**, 76-84.

Bo K, Braekken IH, Majida M, & Engh ME (2009). Constriction of the levator hiatus during instruction of pelvic floor or transversus abdominis contraction: A 4D ultrasound study. *International Urogynecology Journal and Pelvic Floor Dysfunction* **20**, 27-32.

Bo K & Finckenhagen HB (2001). Vaginal palpation of pelvic floor muscle strength: inter-test reproducibility and comparison between palpation and vaginal squeeze pressure.[see comment]. *Acta Obstetricia et Gynecologica Scandinavica* **80**, 883-887.

Bo K, Kvarstein B, Hagen R, & Larsen S (1990a). Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: I. Reliability of vaginal pressure measurements of pelvic floor muscle strength. *Neurourology and Urodynamics* **9**, 471-477.

Bo K, Kvarstein B, Hagen RR, & Larsen S (1990b). Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: II. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourology and Urodynamics* **9**, 479-487.

References

Bo K, Larsen S, & Oseid S (1988). Knowledge about and ability to correct pelvic floor muscle exercises in women with urinary stress incontinence. *Neurourology and Urodynamics* **7**, 261-262.

Bo K & Sherburn M (2005). Evaluation of female pelvic-floor muscle function and strength. [Review] [108 refs]. *Physical Therapy 85(3):269-82*.

Bo K & Talseth T (1996). Long-term effect of pelvic floor muscle exercise 5 years after cessation of organized training. *Obstetrics & Gynecology* **87**, 261-265.

Bower WF, Chase JW, & Stillman BC (2006). Normative pelvic floor parameters in children assessed by transabdominal ultrasound. *Journal of Urology* **176**, 337-341.

Boyles SH, Weber AM, & Meyn L (2003). Procedures for urinary incontinence in the United States, 1979-1997. *American Journal of Obstetrics & Gynecology* **189**, 70-75.

Braekken IH, Majida M, Ellstrom-Engh M, Dietz HP, Umek W, & Bo K (2008). Test-retest and intra-observer repeatability of two-, three- and four-dimensional perineal ultrasound of pelvic floor muscle anatomy and function. *International Urogynecology Journal* **19**, 227-235.

Braekken IH, Majida M, Engh ME, & Bo K (2009). Test-retest reliability of pelvic floor muscle contraction measured by 4D ultrasound. *Neurourology & Urodynamics* **28**, 68-73.

Brink CA, Wells TJ, Sampselle CM, Taillie ER, & Mayer R (1994). A digital test for pelvic muscle strength in women with urinary incontinence. *Nursing Research* **43**, 352-356.

Buchsbaum GM & Duecy EE (2008). Incontinence and pelvic organ prolapse in parous/nulliparous pairs of identical twins. *Neurourology & Urodynamics* **27**, 496-498.

Buchsbaum GM, Duecy EE, Kerr LA, Huang LS, & Guzick DS (2005). Urinary incontinence in nulliparous women and their parous sisters. *Obstetrics & Gynecology* **106**, 1253-1258.

Bump RC, Hurt WG, Fantl JA, & Wyman JF (1991). Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. *American Journal of Obstetrics & Gynecology* **165**, 322-327.

Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JOL, Klarskov P, Shull BL, & Smith ARB (1996). The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *American Journal of Obstetrics and Gynecology* **175**, 10-17.

References

Bump RC & Norton PA (1998). Epidemiology and natural history of pelvic floor dysfunction. [Review] [129 refs]. *Obstetrics & Gynecology Clinics of North America* **25**, 723-746.

Burgio KL, Zyczynski H, Locher JL, Richter HE, Redden DT, & Wright KC (2003). Urinary incontinence in the 12-month postpartum period. *Obstetrics & Gynecology* **102**, 1291-1298.

Cammu H, Van NM, Derde MP, DeBruyne R, & Amy JJ (1991). Pelvic physiotherapy in genuine stress incontinence. *Urology* **38**, 332-337.

Cespedes I, Ophir J, Ponnekanti H, & Maklad N (1993). Elastography: elasticity imaging using ultrasound with application to muscle and breast in vivo. *Ultrasonic Imaging* **15**, 73-88.

Chen EJ, Jenkins WK, & O'Brien WD, Jr. (1995). Performance of ultrasonic speckle tracking in various tissues. *Journal of the Acoustical Society of America* **98**, 1273-1278.

Chen GD, Su TH, & Lin LY (1997). Applicability of perineal sonography in anatomical evaluation of bladder neck in women with and without genuine stress incontinence. *Journal of Clinical Ultrasound* **25**, 189-194.

Cochlin DL, Ganatra RH, & Griffiths DF (2002). Elastography in the detection of prostatic cancer.[see comment]. *Clinical Radiology* **57**, 1014-1020.

Constantinou CE & Govan DE (1982). Spatial distribution and timing of transmitted and reflexly generated urethral pressures in healthy women. *Journal of Urology 127(5):964-9*.

Constantinou CE, Hvistendahl G, Ryhammer A, Nagel LL, & Djurhuus JC. Determining the displacement of the pelvic floor and pelvic organs during voluntary contractions using magnetic resonance imaging in younger and older women. BJU International 90, 408-414. 2002.
Ref Type: Journal (Full)

Constantinou CE & Omata S (2007). Direction sensitive sensor probe for the evaluation of voluntary and reflex pelvic floor contractions. *Neurourology and Urodynamics* **26**, 386-391.

Costantini S, Esposito F, Nadalini C, Lijoi D, Morano S, Lantieri P, & Mistrangelo E (2006). Ultrasound imaging of the female perineum: the effect of vaginal delivery on pelvic floor dynamics. *Ultrasound in Obstetrics & Gynecology 27(2):183-7*.

Costantini S, Nadalini C, Esposito F, Valenzano MM, Risso D, Lantieri P, & Mistrangelo E (2005). Perineal ultrasound evaluation of the urethrovesical junction angle and urethral mobility in nulliparous women and women following vaginal delivery. *International Urogynecology Journal* **16**, 455-459.

Creighton SM, Pearce JM, & Stanton SL (1992). Perineal video-ultrasonography in the assessment of vaginal prolapse: early observations. *British Journal of Obstetrics & Gynaecology* **99**, 310-313.

Cresswell AG, Grundstrom H, & Thorstensson A (1992). Observations on intra-abdominal pressure and patterns of abdominal intra-muscular activity in man. *Acta Physiologica Scandinavica* **144**, 409-418.

Daneshgari F & Moore C (2006). Advancing the understanding of pathophysiological rationale for the treatment of stress urinary incontinence in women: The 'trampoline theory'. *BJU International* **98**, 8-14.

Deen KI, Kumar D, Williams JG, Olliff J, & Keighley MR (1993). Anal sphincter defects. Correlation between endoanal ultrasound and surgery. *Annals of Surgery* **218**, 201-205.

Deffieux T, Gennisson JL, Tanter M, & Fink M (2008). Assessment of the mechanical properties of the musculoskeletal system using 2-D and 3-D very high frame rate ultrasound. *IEEE Transactions on Ultrasonics Ferroelectrics & Frequency Control* **55**, 2177-2190.

Deffieux X, Hubeaux K, Porcher R, Ismael SS, Raibaut P, & Amarenco G (2007). Pelvic floor muscle activity during coughing: altered pattern in women with stress urinary incontinence. *Urology* **70**, 443-447.

Deindl FM, Vodusek DB, Hesse U, & Schussler B (1994). Pelvic floor activity patterns: comparison of nulliparous continent and parous urinary stress incontinent women. A kinesiological EMG study. *British Journal of Urology 73(4):413-7.*

Delancey JO (1988). Structural aspects of the extrinsic continence mechanism. *Obstetrics & Gynecology* **72**, t-301.

DeLancey JO (1988). Structural aspects of the extrinsic continence mechanism. *Obstetrics & Gynecology* **72**, t-301.

DeLancey JO (2005). The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment. [Review] [9 refs]. *American Journal of Obstetrics & Gynecology* **192**, 1488-1495.

DeLancey JOL (1990). Anatomy and physiology of urinary continence. *Clinical Obstetrics and Gynecology* **33**, 298-307.

DeLancey JOL (1994). Structural support of the urethra as it relates to stress urinary incontinence: The hammock hypothesis. *American Journal of Obstetrics and Gynecology* **170**, 1713-1723.

DeLancey JOL (1999). Structural anatomy of the posterior pelvic compartment as it relates to rectocele. *American Journal of Obstetrics and Gynecology* **180**, 815-823.

DeLancey JOL & Hurd WW (1998). Size of the urogenital hiatus in the levator ani muscles in normal women and women with pelvic organ prolapse. *Obstetrics and Gynecology* **91**, 364-368.

DeLancey JOL, Trowbridge ER, Miller JM, Morgan DM, Guire K, Fenner DE, Weadock WJ, & Ashton-Miller JA (2008). Stress Urinary Incontinence: Relative Importance of Urethral Support and Urethral Closure Pressure. *Journal of Urology* **179**, 2286-2290.

Delancey JOL & Ashton-miller JA (2004). Pathophysiology of adult urinary incontinence. *Gastroenterology* **126**, S23-S32.

DeTayrac R., Deffieux X, Resten A, Doumerc S, Jouffroy C, & Fernandez H (2006). A transvaginal ultrasound study comparing transobturator tape and tension-free vaginal tape after surgical treatment of female stress urinary incontinence. *International Urogynecology Journal and Pelvic Floor Dysfunction* **17**, 466-471.

Devreese A, Staes F, De WW, Feys H, Van AA, Penninckx F, & Vereecken R (2004). Clinical evaluation of pelvic floor muscle function in continent and incontinent women. *Neurourology & Urodynamics* **23**, 190-197.

Dietz HP (2004). Levator function before and after childbirth. *Australian & New Zealand Journal of Obstetrics & Gynaecology* **44**, 19-23.

Dietz HP & Clarke B (2001a). The influence of posture on perineal ultrasound imaging parameters. *International Urogynecology Journal* **12**, 104-106.

Dietz HP & Clarke B (2001b). The urethral pressure profile and ultrasound imaging of the lower urinary tract. *International Urogynecology Journal* **12**, 38-41.

Dietz HP, Hyland G, & Hay-Smith J (2006). The assessment of levator trauma: a comparison between palpation and 4D pelvic floor ultrasound. *Neurourology & Urodynamics* **25**, 424-427.

Dietz HP, Jarvis SK, & Vancaillie TG (2002). The assessment of levator muscle strength: a validation of three ultrasound techniques. *International Urogynecology Journal 13(3):156-9; discussion 159*.

Dietz HP & Shek C (2008). Levator avulsion and grading of pelvic floor muscle strength. *International Urogynecology Journal* **19**, 633-636.

Dietz HP, Shek C, & Clarke B (2005). Biometry of the pubovisceral muscle and levator hiatus by three-dimensional pelvic floor ultrasound. *Ultrasound in Obstetrics & Gynecology* **25**, 580-585.

Dietz HP & Wilson PD (1998). Anatomical assessment of the bladder outlet and proximal urethra using ultrasound and videocystourethrography. *International Urogynecology Journal* **9**, 365-369.

Dietz HP & Wilson PD (1999). The influence of bladder volume on the position and mobility of the urethrovesical junction. *International Urogynecology Journal 10(1):3-6*.

Dietz HP, Wilson PD, & Clarke B (2001). The use of perineal ultrasound to quantify levator activity and teach pelvic floor muscle exercises. *International Urogynecology Journal* **12**, 166-168.

Digesu GA, Robinson D, Cardozo L, & Khullar V (2009). Three-dimensional ultrasound of the urethral sphincter predicts continence surgery outcome. *Neurourology & Urodynamics* **28**, 90-94.

Dougherty MC, Abrams R, & McKey PL (1986). An instrument to assess the dynamic characteristics of the circumvaginal musculature. *Nursing Research* **35**, 202-206.

Dumoulin C, Bourbonnais D, & Lemieux MC (2003). Development of a dynamometer for measuring the isometric force of the pelvic floor musculature. *Neurourology & Urodynamics 22(7):648-53*.

Dumoulin C, Gravel D, Bourbonnais D, Lemieux MC, & Morin M (2004a). Reliability of dynamometric measurements of the pelvic floor musculature. *Neurourology & Urodynamics* **23**, 134-142.

Dumoulin C & Hay-Smith J (2008). Pelvic floor muscle training versus no treatment for urinary incontinence in women. A Cochrane systematic review. [Review] [32 refs]. *European journal of physical & rehabilitation medicine* **44**, 47-63.

Dumoulin C, Lemieux MC, Bourbonnais D, Gravel D, Bravo G, & Morin M (2004b). Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. *Obstetrics & Gynecology* **104**, 504-510.

Dumoulin C, Lemieux MC, Bourbonnais D, Gravel D, Bravo G, & Morin M (2004c). Physiotherapy for persistent postnatal stress urinary incontinence: a randomized controlled trial. *Obstetrics & Gynecology* **104**, 504-510.

Enck P & Vodusek DB (2006). Electromyography of pelvic floor muscles. *Journal of Electromyography and Kinesiology* **16**, 568-577.

Enhorning G (1961). Simultaneous recording of intravesical and intra-urethral pressure. A study on urethral closure in normal and stress incontinent women. *Acta Chirurgica Scandinavica - Supplementum Suppl 276:1-68, 1961* **1-68**.

Farron J, Varghese T, & Thelen DG (2009). Measurement of tendon strain during muscle twitch contractions using ultrasound elastography. *IEEE Transactions on Ultrasonics Ferroelectrics & Frequency Control* **56**, 27-35.

Finch E, Brooks D, Stratford P, & Mayo N (2002). *Physical Rehabilitation Outcome Measures*, 2nd ed.

Foldspang A, Mommsen S, Lam GW, & Elving L (1992). Parity as a correlate of adult female urinary incontinence prevalence. *Journal of Epidemiology & Community Health* **46**, 595-600.

Foulot H, Uzan I, Chopin N, Borghese B, & Chapron C (2007). Monarc transobturator sling system for the treatment of female urinary stress incontinence: results of a post-operative transvaginal ultrasonography. *International Urogynecology Journal* **18**, 857-861.

Frawley HC, Galea MP, Phillips BA, Sherburn M, & Bo K (2006a). Effect of test position on pelvic floor muscle assessment. *International Urogynecology Journal* **17**, 365-371.

Frawley HC, Galea MP, Phillips BA, Sherburn M, & Bo K (2006b). Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourology & Urodynamics* **25**, 236-242.

Frawley HC, Galea MP, Phillips BA, Sherburn M, & Bo K (2006c). Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourology & Urodynamics* **25**, 236-242.

References

Gennisson JL, Catheline S, Chaffai S, & Fink M (2003). Transient elastography in anisotropic medium: application to the measurement of slow and fast shear wave speeds in muscles. *Journal of the Acoustical Society of America* **114**, 536-541.

Gerrard ER, Jr., Lloyd LK, Kubricht WS, & Kolettis PN (2003). Transvaginal ultrasound for the diagnosis of urethral diverticulum. *Journal of Urology* **169**, 1395-1397.

Gerrits M, Avery T, & Lagro-Janssen A (2008). Urinary incontinence management in women: audit in general practice. *Journal of Evaluation in Clinical Practice* **14**, 836-838.

Gilja OH, Heimdal A, Hausken T, Gregersen H, Matre K, Berstad A, & Odegaard S (2002). Strain during gastric contractions can be measured using Doppler ultrasonography. *Ultrasound in Medicine & Biology* **28**, 1457-1465.

Gordon D, Pearce M, Norton P, & Stanton SL (1989). Comparison of ultrasound and lateral chain urethrocystography in the determination of bladder neck descent. *American Journal of Obstetrics & Gynecology* **160**, 182-185.

Gosling JA, Dixon JS, Critchley HO, & Thompson SA (1981). A comparative study of the human external sphincter and periurethral levator ani muscles. *British Journal of Urology* **53**, 35-41.

Gottlieb D, Dvir Z, Golomb J, & Beer-Gabel M (2009). Reproducibility of ultrasonic measurements of pelvic floor structures in women suffering from urinary incontinence. *International Urogynecology Journal* **20**, 309-312.

Grigorescu BA, Lazarou G, Olson TR, Downie SA, Powers K, Greston WM, & Mikhail MS (2008). Innervation of the levator ani muscles: description of the nerve branches to the pubococcygeus, iliococcygeus, and puborectalis muscles. *International Urogynecology Journal* **19**, 107-116.

Grimby A, Milsom I, Molander U, Wiklund I, & Ekelund P (1993). The influence of urinary incontinence on the quality of life of elderly women. *Age & Ageing* **22**, 82-89.

Groutz A, Gordon D, Keidar R, Lessing JB, Wolman I, David MP, & Chen B (1999). Stress urinary incontinence: prevalence among nulliparous compared with primiparous and grand multiparous premenopausal women.[see comment]. *Neurourology & Urodynamics* **18**, 419-425.

Groutz A, Helpman L, Gold R, Pauzner D, Lessing JB, & Gordon D (2007). First vaginal delivery at an older age: Does it carry an extra risk for the development of stress urinary incontinence? *Neurourology & Urodynamics* **26**, 779-782.

Guaderrama NM, Liu J, Nager CW, Pretorius DH, Sheean G, Kassab G, & Mittal RK (2005a). Evidence for the innervation of pelvic floor muscles by the pudendal nerve. *Obstetrics & Gynecology* **106**, 774-781.

Guaderrama NM, Nager CW, Liu J, Pretorius DH, & Mittal RK (2005b). The vaginal pressure profile. *Neurourology and Urodynamics* **24**, 243-247.

Gufler H, Ohde A, Grau G, & Grossmann A (2004). Colpocystoproctography in the upright and supine positions correlated with dynamic MRI of the pelvic floor. *European Journal of Radiology* **51**, 41-47.

Gunnarsson M & Mattiasson A (1999). Female stress, urge, and mixed urinary incontinence are associated with a chronic and progressive pelvic floor/vaginal neuromuscular disorder: An investigation of 317 healthy and incontinent women using vaginal surface electromyography. *Neurourology & Urodynamics* **18**, 613-621.

Han L, Noble JA, & Burcher M (2003). A novel ultrasound indentation system for measuring biomechanical properties of in vivo soft tissue. *Ultrasound in Medicine & Biology* **29**, 813-823.

Hannestad YS, Lie RT, Rortveit G, & Hunskaar S (2004). Familial risk of urinary incontinence in women: population based cross sectional study. *BMJ* **329**, 889-891.

Hannestad YS, Rortveit G, Sandvik H, Hunskaar S, & Norwegian EPINCONT study.Epidemiology of Incontinence in the County of Nord-Trondelag (2000). A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trondelag. *Journal of Clinical Epidemiology* **53**, 1150-1157.

Hay-Smith EJC., Herbison G.P, & Wilson P.D. Pelvic Floor Muscle Training for Women with Symptoms Of Stress Urinary Incontinence: A Randomised Trial Comparing Strengthening and Motor Relearning Approaches. Neurourology & Urodynamics . 2002. Ref Type: Abstract

Hay-Smith J, Morkved S, Fairbrother KA, & Herbison GP (2008). Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. [Review] [74 refs]. *Cochrane Database of Systematic Reviews (4):CD007471, 2008* CD007471.

Hedrick W (2004). *Ultrasound Physics and Instrumentation*, 4th ed. Mosby.

Heimdal A, Stoylen A, Torp H, & Skjaerpe T (1998). Real-time strain rate imaging of the left ventricle by ultrasound. *Journal of the American Society of Echocardiography* **11**, 1013-1019.

Hemborg B, Moritz U, & Lowing H (1985). Intra-abdominal pressure and trunk muscle activity during lifting. IV. The causal factors of the intra-abdominal pressure rise. *Scandinavian Journal of Rehabilitation Medicine* **17**, 25-38.

Henalla SM, Kirwan P, Castleden CM, Hutchins CJ, & Breeson AJ (1988). The effect of pelvic floor exercises in the treatment of genuine urinary stress incontinence in women at two hospitals. *British Journal of Obstetrics & Gynaecology 95(6):602-6*.

Herschorn S (2004). Female pelvic floor anatomy: the pelvic floor, supporting structures, and pelvic organs. *Reviews in Urology* **6**, Suppl-S10.

Hodges PW & Gandevia SC (2000). Changes in intra-abdominal pressure during postural and respiratory activation of the human diaphragm. *Journal of Applied Physiology* **89**, 967-976.

Hodges PW & Richardson CA (1998). Delayed postural contraction of transversus abdominis in low back pain associated with movement of the lower limb. *Journal of Spinal Disorders* **11**, 46-56.

Hodges PW, Sapsford R, & Pengel LH (2007). Postural and respiratory functions of the pelvic floor muscles. *Neurourology & Urodynamics* **26**, 362-371.

Hoff Brækken I, Majida M, Ellstrom-Engh M, & Bo K (2009). Test-Retest Reliability of Pelvic Floor Muscle Contraction Measured by 4D Ultrasound. *Neurourology and Urodynamics* **28:** 68-73.

Howard D, Miller JM, DeLancey JO, & Ashton-Miller JA (2000). Differential effects of cough, valsalva, and continence status on vesical neck movement. *Obstetrics & Gynecology* **95**, 535-540.

Huang WC, Yang SH, & Yang JM (2006). Anatomical and functional significance of urogenital hiatus in primary urodynamic stress incontinence. *Ultrasound in Obstetrics & Gynecology* **27**, 71-77.

Huang WC, Yang SH, & Yang JM (2007). Three-dimensional transperineal sonographic characteristics of the anal sphincter complex in nulliparous women. *Ultrasound in Obstetrics & Gynecology* **30**, 210-220.

Hundley AF, Wu JM, & Visco AG (2005). A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. *American Journal of Obstetrics & Gynecology* **192**, 1583-1591.

Insana MF, Wagner RF, Garra BS, Momenan R, & Shawker TH (1986). Pattern recognition methods for optimizing multivariate tissue signatures in diagnostic ultrasound. *Ultrasonic Imaging* **8**, 165-180.

Isherwood PJ & Rane A (2000). Comparative assessment of pelvic floor strength using a perineometer and digital examination. *BJOG: An International Journal of Obstetrics & Gynaecology* **107**, 1007-1011.

Jeyaseelan SM, Haslam J, Winstanley J, Roe BH, & Oldham JA (2001). Digital vaginal assessment: An inter-tester reliability study. *Physiotherapy (London)* **87**, 243-250.

Jones R, Peng Q, & Constantinou C (2006). The clinical application of two-dimensional ultrasound image processing in identifying the response of urogenital structures to voluntary and reflex pelvic floor muscle contractions. *Journal - Association of Chartered Physiotherapists in Women's Health* **98:28-35.**, 28-35.

Kearney R, Miller JM, & DeLancey JO (2006). Interrater reliability and physical examination of the pubovisceral portion of the levator ani muscle, validity comparisons using MR imaging. *Neurourology & Urodynamics* **25**, 50-54.

Kearney R, Sawhney R, & DeLancey JOL (2004). Levator ani muscle anatomy evaluated by origin-insertion pairs. *Obstetrics and Gynecology* **104**, 168-173.

Kegal AH (1948). Progressive resistance exercise in the functional restoration of the perineal muscles. *Am J Obstet Gynecol* **56**, 238-249.

Kelly M, Tan BK, Thompson J, Carroll S, Follington M, Arndt A, & Seet M (2007). Healthy adults can more easily elevate the pelvic floor in standing than in crook-lying: an experimental study. *Australian Journal of Physiotherapy* **53**, 187-191.

Kenton K & Brubaker L (2002). Relationship between levator ani contraction and motor unit activation in the urethral sphincter. *American Journal of Obstetrics & Gynecology* **187**, 403-406.

Kerschan-Schindl K, Uher E, Wiesinger G, Kaider A, Ebenbichler G, Nicolakis P, Kollmitzer J, Preisinger E, & Fialka-Moser V (2002). Reliability of pelvic floor muscle strength measurement in elderly incontinent women. *Neurourology & Urodynamics* **21**, 42-47.

Kessler R & Constantinou CE (1986). Internal urethrotomy in girls and its impact on the urethral intrinsic and extrinsic continence mechanisms. *Journal of Urology 136(6):1248-53*.

Koelbl H, Bernaschek G, & Wolf G (1988). A comparative study of perineal ultrasound scanning and urethrocystography in patients with genuine stress incontinence. *Archives of Gynecology & Obstetrics* **244**, 39-45.

Koelbl H, Mostwin JL, & Boiteux JP (2002). Pathophysiology. *Incontinence 2nd International Consultation on Incontinence* 203-265.

Kondo Y, Homma Y, Takahashi S, Kitamura T, & Kawabe K (2001). Transvaginal ultrasound of urethral sphincter at the mid urethra in continent and incontinent women. *Journal of Urology* **165**, 149-152.

Koppenhaver SL, Hebert JJ, Fritz JM, Parent EC, Teyhen DS, & Magel JS (2009). Reliability of rehabilitative ultrasound imaging of the transversus abdominis and lumbar multifidus muscles. *Archives of Physical Medicine & Rehabilitation* **90**, 87-94.

Kremkau FW (2002). *Diagnostic Ultrasound: Principles and Instruments* Saunders, Philadelphia, PA.

Kruger JA, Dietz HP, & Murphy BA (2007). Pelvic floor function in elite nulliparous athletes. *Ultrasound in Obstetrics & Gynecology* **30**, 81-85.

Kruger JA, Heap SW, Murphy BA, & Dietz HP (2008). Pelvic floor function in nulliparous women using three-dimensional ultrasound and magnetic resonance imaging. *Obstetrics & Gynecology* **111**, 631-638.

Kuh D, Cardozo L, & Hardy R (1999). Urinary incontinence in middle aged women: childhood enuresis and other lifetime risk factors in a British prospective cohort. *Journal of Epidemiology & Community Health* **53**, 453-458.

Landis JR & Koch GG (1977). The measurement of observer agreement for categorical data. *Biometrics* **33**, 159-174.

Langevin HM, Rizzo DM, Fox JR, Badger GJ, Wu J, Konofagou EE, Stevens-Tuttle D, Bouffard NA, & Krag MH (2007). Dynamic morphometric characterization of local connective tissue network structure in humans using ultrasound. *BMC Systems Biology* **1**, 25.

References

Lavin JM, mith ARB, nderson J, rant M, uckley H, ritchley H, & osker GL. The effect of the first pregnancy on the connective tissue of the rectus sheath. Neurourology & Urodynamics.22(4):269-76, 16: 381-382. 1997.
Ref Type: Journal (Full)

Laycock J. The development and validation of a pelvic floor digital assessment scheme. assessment and treatment of Pelvic Floor dysfunction. Neurourology & Urodynamics . 1992. Thesis University of Bradford.
Ref Type: Thesis/Dissertation

Laycock J & Jerwood D (1994). Development of the Bradford perineometer. *Physiotherapy* **80**, 139-143.

Laycock J & Jerwood D (2001). Pelvic floor muscle assessment: The PERFECT scheme. *Physiotherapy Vol 87(12)()(pp 631-642), 2001* 631-642.

Lenth RV. Java Applets for Power and Sample Size . 2006.
Ref Type: Online Source

Lewicky-Gaupp C, Blaivas J, Clark A, McGuire EJ, Schaer G, Tumbarello J, Tunn R, & DeLancey JO (2009). "The cough game": are there characteristic urethrovesical movement patterns associated with stress incontinence? *International Urogynecology Journal* **20**, 171-175.

Lo TS, Horng SG, Liang CC, Lee SJ, & Soong YK (2004). Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. *Urology* **63**, 671-675.

Lo TS, Wang AC, Horng SG, Liang CC, & Soong YK (2001). Ultrasonographic and urodynamic evaluation after tension free vagina tape procedure (TVT). *Acta Obstetricia et Gynecologica Scandinavica* **80**, 65-70.

Lukban J, Whitmore K, Kellogg-Spadt S, Bologna R, Lesher A, & Fletcher E (2001). The effect of manual physical therapy in patients diagnosed with interstitial cystitis, high-tone pelvic floor dysfunction, and sacroiliac dysfunction. *Urology* **57**, Suppl-2.

MacArthur C, Glazener CM, Wilson PD, Lancashire RJ, Herbison GP, & Grant AM (2006). Persistent urinary incontinence and delivery mode history: a six-year longitudinal study. *BJOG: An International Journal of Obstetrics & Gynaecology* **113**, 218-224.

Madill SJ & McLean L (2006). Relationship between abdominal and pelvic floor muscle activation and intravaginal pressure during pelvic floor muscle contractions in healthy continent women. *Neurourology & Urodynamics* **25**, 722-730.

Majida M, Braekken IH, Umek W, Bo K, Benth S, & Engh ME (2009). Interobserver repeatability of three- and four-dimensional transperineal ultrasound assessment of pelvic floor muscle anatomy and function. *Ultrasound in Obstetrics and Gynecology* **33**, 567-573.

Martan A, Masata J, Halaska M, Otcenasek M, & Svabik K (2002). Ultrasound imaging of paravaginal defects in women with stress incontinence before and after paravaginal defect repair. *Ultrasound in Obstetrics & Gynecology* **19**, 496-500.

Martins JAC, Pato MPM, Pires EB, Natal Jorge RM, Parente M, & Mascarenhas T (2007). Finite element studies of the deformation of the pelvic floor. *Reproductive BiomechanicsAnnals of the New York Academy of Sciences* **1101**, -334.

Masata J, Svabik K, Martan A, Drahoradova P, & Pavlikova M (2005). [What ultrasound parameter is optimal in the examination of position and mobility of urethrovesical junction?]. [Czech]. *Ceska Gynekologie* **70**, 280-285.

McGuire EJ (1978). Experimental observations on the integration of bladder and urethral function. *Investigative Urology* **15**, 303-307.

McGuire EJ (1981). Urodynamic findings in patients after failure of stress incontinence operations. *Progress in Clinical & Biological Research* **78**, 351-360.

McGuire EJ, Fitzpatrick CC, Wan J, Bloom D, Sanvordenker J, Ritchey M, & Gormley EA (1993). Clinical assessment of urethral sphincter function. *Journal of Urology* **150**, 1452-1454.

Messelink B, Benson T, Berghmans B, Bo K, Corcos J, Fowler C, Laycock J, Lim PH, van LR, Nijeholt GL, Pemberton J, Wang A, Watier A, & Van KP (2005). Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. *Neurourology & Urodynamics* **24**, 374-380.

Meyer S, De GP, Schreyer A, & Caccia G (1996). The assessment of bladder neck position and mobility in continent nullipara, mulitpara, forceps-delivered and incontinent women using perineal ultrasound: a future office procedure? *International Urogynecology Journal* **7**, 138-146.

Miller JM, Ashton-Miller JA, DeLancey JOL, & Carchidi LT (1997). Does a three month pelvic muscle exercise intervention improve the effectiveness of the knack in reducing cough induced urine loss on standing stress test? *International Urogynecology Journal* 253.

Miller JM, Ashton-Miller JA, & DeLancey JO (1998). A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *Journal of the American Geriatrics Society* **46**, 870-874.

Miller JM, Ashton-Miller JA, Perruchini D, & DeLancey JO (2007). Test-retest reliability of an instrumented speculum for measuring vaginal closure force. *Neurourology & Urodynamics* **26**, 858-863.

Miller JM, Perucchini D, Carchidi LT, DeLancey JO, & Ashton-Miller J (2001). Pelvic floor muscle contraction during a cough and decreased vesical neck mobility. *Obstetrics & Gynecology* **97**, 255-260.

Miller JM, Sampselle C, Ashton-Miller J, Hong GR, & DeLancey JO (2008). Clarification and confirmation of the Knack maneuver: the effect of volitional pelvic floor muscle contraction to preempt expected stress incontinence. *International Urogynecology Journal* **19**, 773-782.

Miller JM, Umek WH, DeLancey JO, & Ashton-Miller JA (2004). Can women without visible pubococcygeal muscle in MR images still increase urethral closure pressures? *American Journal of Obstetrics & Gynecology* **191**, 171-175.

Morgan DM, Kaur G, Hsu Y, Fenner DE, Guire K, Miller J, Ashton-Miller JA, & DeLancey JO (2005). Does vaginal closure force differ in the supine and standing positions? *American Journal of Obstetrics & Gynecology* **192**, 1722-1728.

Morin M, Bourbonnais D, Gravel D, Dumoulin C, & Lemieux MC (2004a). Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements. *Neurourology & Urodynamics* **23**, 668-674.

Morin M, Dumoulin C, Bourbonnais D, Gravel D, & Lemieux MC (2004b). Pelvic floor maximal strength using vaginal digital assessment compared to dynamometric measurements. *Neurourology & Urodynamics* **23**, 336-341.

Morin M, Dumoulin C, Gravel D, Bourbonnais D, & Lemieux MC (2004c). Reliability of speed of contraction and endurance dynamometric measurements of the pelvic floor musculature in stress incontinent parous women. *Neurourology & Urodynamics* **26**, 397-403.

References

Morin M, Gravel D, Bourbonnais D, Dumoulin C, & Ouellet S (2008). Reliability of dynamometric passive properties of the pelvic floor muscles in postmenopausal women with stress urinary incontinence. *Neurourology & Urodynamics* **27**, 819-825.

Morin M, Gravel D, Ouellet S, Dumoulin C, & Bourbonnais D (2006). Influence of increased cough intensity on the activation timing and contractile force of associated pelvic floor muscle contraction in continent women. *Neurourology & Urodynamics* **25**, 530-531.

Morkved S & Bo K (1997). The effect of postpartum pelvic floor muscle exercise in the prevention and treatment of urinary incontinence. *International Urogynecology Journal* **8**, 217-222.

Morkved S, Bo K, & Fjortoft T (2002). Effect of adding biofeedback to pelvic floor muscle training to treat urodynamic stress incontinence.[see comment]. *Obstetrics & Gynecology* **100**, 730-739.

Morkved S, Salvesen KA, Bo K, & Eik-Nes S (2004). Pelvic floor muscle strength and thickness in continent and incontinent nulliparous pregnant women. *International Urogynecology Journal* **15**, 384-389.

Moseley GL, Hodges PW, & Gandevia SC (2002a). Deep and superficial fibers of the lumbar multifidus muscle are differentially active during voluntary arm movements. *Spine* **27**, E29-E36.

Moseley GL, Hodges PW, & Gandevia SC (2002b). Deep and superficial fibers of the lumbar multifidus muscle are differentially active during voluntary arm movements. *Spine* **27**, E29-E36.

Mostwin JL (1991). Current concepts of female pelvic anatomy and physiology. *Urologic Clinics of North America* **18**, 175-195.

Mouritsen L (1997). Techniques for imaging bladder support. *Acta Obstetricia et Gynecologica Scandinavica - Supplement* **166**, 48-49.

Mouritsen L & Rasmussen A (1993). Bladder neck mobility evaluated by vaginal ultrasonography. *British Journal of Urology* **71**, 166-171.

Netter FH (2006). *Atlas of Human Anatomy*, 4th ed. Saunders.

Neumann P & Gill V (2002). Pelvic floor and abdominal muscle interaction: EMG activity and intra-abdominal pressure. *International Urogynecology Journal* **13**, 125-132.

Nguyen JK, Gunn GC, & Bhatia NN (2002). The effect of patient position on leak-point pressure measurements in women with genuine stress incontinence. *International Urogynecology Journal* **13**, 9-14.

Nitti VW (2001). The prevalence of urinary incontinence. *Reviews in Urology* **3**, Suppl-6.

Noble JG, Dixon PJ, Rickards D, & Fowler CJ (1995). Urethral sphincter volumes in women with obstructed voiding and abnormal sphincter electromyographic activity. *British Journal of Urology* **76**, 741-746.

Norton PA & Baker JE (1994). Postural changes can reduce leakage in women with stress urinary incontinence. *Obstetrics & Gynecology* **84**, 770-774.

Nygaard I, Barber MD, Burgio KL, Kenton K, Meikle S, Schaffer J, Spino C, Whitehead WE, Wu J, Brody DJ, & Pelvic Floor DN (2008). Prevalence of symptomatic pelvic floor disorders in US women. *JAMA* **300**, 1311-1316.

O'Sullivan PB, Beales DJ, Beetham JA, Cripps J, Graf F, Lin IB, Tucker B, & Avery A (2002). Altered motor control strategies in subjects with sacroiliac joint pain during the active straight-leg-raise test. *Spine* **27**, E1-E8.

Oelrich TM (1983). The striated urogenital sphincter muscle in the female. *Anatomical Record* **205**, 223-232.

Oliveira E, Castro RA, Takano CC, Bezerra LR, Sartori MG, Lima GR, Baracat EC, & Girao MJ (2007). Ultrasonographic and Doppler velocimetric evaluation of the levator ani muscle in premenopausal women with and without urinary stress incontinence. *European Journal of Obstetrics, Gynecology, & Reproductive Biology* **133**, 213-217.

Olsen AL, Smith VJ, Bergstrom JO, Colling JC, & Clark AL (1997). Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics & Gynecology* **89**, 501-506.

Ophir J, Cespedes I, Ponnekanti H, Yazdi Y, & Li X (1991). Elastography: a quantitative method for imaging the elasticity of biological tissues. *Ultrasonic Imaging* **13**, 111-134.

Orno AK & Dietz HP (2007). Levator co-activation is a significant confounder of pelvic organ descent on Valsalva maneuver. *Ultrasound in Obstetrics & Gynecology* **30**, 346-350.

Orno AK, Marsal K, & Herbst A (2008). Ultrasonographic anatomy of perineal structures during pregnancy and immediately following obstetric injury. *Ultrasound in Obstetrics & Gynecology* **32**, 527-534.

Ostrzenski A & Osborne NG (1998). Ultrasonography as a screening tool for paravaginal defects in women with stress incontinence: a pilot study. *International Urogynecology Journal* **9**, 195-199.

Otcenasek M, Krofta L, Baca V, Grill R, Kucera E, Herman H, Vasicka I, Drahonovsky J, & Feyereisl J (2007). Bilateral avulsion of the puborectal muscle: Magnetic resonance imaging-based three-dimensional reconstruction and comparison with a model of a healthy nulliparous woman. *Ultrasound in Obstetrics and Gynecology* **29**, 692-696.

Otsu N & Threshold A (1979). Selection method from Gray-Level Histograms. *IEEE Trans Syst Man Cybern* **9**, 62-66.

Peng Q, Jones R, Shishido K, & Constantinou CE (2007a). Ultrasound evaluation of dynamic responses of female pelvic floor muscles. *Ultrasound in Medicine & Biology Vol 33(3)()(pp 342-352), 2007* 342-352.

Peng Q, Jones R, Shishido K, Omata S, & Constantinou CE (2007b). Spatial distribution of vaginal closure pressures of continent and stress urinary incontinent women. *Physiological Measurement* **28**, 1429-1450.

Peng Q, Jones R, Shishido K, Omata S, & Constantinou CE (2007c). Spatial distribution of vaginal closure pressures of continent and stress urinary incontinent women. *Physiological Measurement* **28**, 1429-1450.

Peng Q, Jones RC, & Constantinou CE (2006). 2D Ultrasound image processing in identifying responses of urogenital structures to pelvic floor muscle activity. *Annals of Biomedical Engineering* **34**, 477-493.

Perucchini D, DeLancey JO, shton-Miller JA, Galecki A, & Schaer GN (2002a). Age effects on urethral striated muscle. II. Anatomic location of muscle loss. *American Journal of Obstetrics & Gynecology* **186**, 356-360.

Perucchini D, DeLancey JOL, Ashton-Miller JA, Peschers U, & Kataria T (2002b). Age effects on urethral striated muscle: I. Changes in number and diameter of striated muscle fibers in the ventral urethra. *American Journal of Obstetrics and Gynecology* **186**, 351-355.

Peschers U, Schaer G, Anthuber C, DeLancey JO, & Schuessler B (1996). Changes in vesical neck mobility following vaginal delivery. *Obstetrics & Gynecology* **88**, 1001-1006.

Peschers UM, DeLancey JO, Fritsch H, Quint LE, & Prince MR (1997a). Cross-sectional imaging anatomy of the anal sphincters. *Obstetrics & Gynecology* **90**, 839-844.

Peschers UM & DeLancey JOL (2008). Anatomy. In *Therapeutic Management of Incontinence and Pelvic Pain*, eds. Haslam J & Laycock J, pp. 9-20. Springer.

Peschers UM, Fanger G, Schaer GN, Vodusek DB, DeLancey JO, & Schuessler B (2001a). Bladder neck mobility in continent nulliparous women. *BJOG: An International Journal of Obstetrics & Gynaecology* **108**, 320-324.

Peschers UM, Gingelmaier A, Jundt K, Leib B, & Dimpfl T (2001b). Evaluation of pelvic floor muscle strength using four different techniques. *International Urogynecology Journal* **12**, 27-30.

Peschers UM, Schaer GN, DeLancey JO, & Schuessler B (1997b). Levator ani function before and after childbirth. *British Journal of Obstetrics & Gynaecology* **104**, 1004-1008.

Peschers UM, Vodusek DB, Fanger G, Schaer GN, DeLancey JO, & Schuessler B (2001c). Pelvic muscle activity in nulliparous volunteers. *Neurourology & Urodynamics* **20**, 269-275.

Petros PE (2007). The anatomy and dynamics of pelvic floor function and dysfunction. In *The Female Pelvic Floor Function dysfunction and management according to the integral theory* Springer, Heidelberg.

Petros PE & Ulmsten UI (1990). An integral theory of female urinary incontinence. Experimental and clinical considerations. [Review] [46 refs]. *Acta Obstetricia et Gynecologica Scandinavica - Supplement* **153**, 7-31.

Pool-Goudzwaard A, van Dijke GH, van Gurp M, Mulder P, Snijders C, & Stoeckart R (2004). Contribution of pelvic floor muscles to stiffness of the pelvic ring. *Clinical Biomechanics* 564-571.

Pregazzi R, Sartore A, Bortoli P, Grimaldi E, Troiano L, & Guaschino S (2002). Perineal ultrasound evaluation of urethral angle and bladder neck mobility in women with stress urinary incontinence. *BJOG: an International Journal of Obstetrics & Gynaecology 109(7):821-7.*

Quinn MJ, Beynon J, Mortensen NJ, & Smith PJ (1988). Transvaginal endosonography: a new method to study the anatomy of the lower urinary tract in urinary stress incontinence. *British Journal of Urology* **62**, 414-418.

Rahmanian S, Jones R, Peng Q, & Constantinou CE (2008). Visualization of biomechanical properties of female pelvic floor function using video motion tracking of ultrasound imaging. *Studies in Health Technology & Informatics* **132**, 390-395.

References

Rankin G & Stokes M (1998). Reliability of assessment tools in rehabilitation: an illustration of appropriate statistical analyses. *Clinical Rehabilitation* **12**, 187-199.

Rankin G, Stokes M, & Newham DJ (2006). Abdominal muscle size and symmetry in normal subjects. *Muscle & Nerve* **34**, 320-326.

Reddy AP, DeLancey JO, Zwica LM, & Ashton-Miller JA (2001). On-screen vector-based ultrasound assessment of vesical neck movement. *American Journal of Obstetrics & Gynecology* **185**, 65-70.

Reed H, Freeman RM, Waterfield A, & Adekanmi O (2004). Prevalence of bladder neck mobility in asymptomatic non-pregnant nulliparous volunteers. *BJOG: An International Journal of Obstetrics & Gynaecology* **111**, 172-175.

Reisinger E & Stummvoll W (2006). Visualization of the endopelvic fascia by transrectal three-dimensional ultrasound. *International Urogynecology Journal* **17**, 165-169.

Richardson AC (1996). Female pelvic floor support defects. *International Urogynecology Journal* **7**, 241.

Richardson AC, Lyon JB, & Williams NL (1976). A new look at pelvic relaxation. *American Journal of Obstetrics and Gynecology* **126**, 568-573.

Robinson D, Anders K, Cardozo L, Bidmead J, Toozs-Hobson P, & Khullar V (2002). Can ultrasound replace ambulatory urodynamics when investigating women with irritative urinary symptoms? *BJOG: An International Journal of Obstetrics & Gynaecology* **109**, 145-148.

Rortveit G, Daltveit AK, Hannestad YS, & Hunskaar S (2003). Vaginal delivery parameters and urinary incontinence: the Norwegian EPINCONT study. *American Journal of Obstetrics & Gynecology* **189**, 1268-1274.

Rortveit G, Hannestad YS, Daltveit AK, & Hunskaar S (2001). Age- and type-dependent effects of parity on urinary incontinence: the Norwegian EPINCONT study. *Obstetrics & Gynecology* **98**, 1004-1010.

Salmons S (1995). *Gray's Anatomy of the Human Body*, 38th ed., pp. 737-900. Churchill Livingstone, New York.

Sandvik H, Seim A, Vanvik A, & Hunskaar S (2000). A severity index for epidemiological surveys of female urinary incontinence: comparison with 48-hour pad-weighing tests. *Neurourology & Urodynamics* **19**, 137-145.

Sapsford RR & Hodges PW (2001). Contraction of the pelvic floor muscles during abdominal maneuvers. *Archives of Physical Medicine & Rehabilitation* **82**, 1081-1088.

Sapsford RR, Hodges PW, Richardson CA, Cooper DH, Markwell SJ, & Jull GA (2001). Co-activation of the abdominal and pelvic floor muscles during voluntary exercises. *Neurourology & Urodynamics* **20**, 31-42.

Sarlos D, Kuronen M, & Schaer GN (2003). How does tension-free vaginal tape correct stress incontinence? investigation by perineal ultrasound. *International Urogynecology Journal* **14**, 395-398.

Sarnelli G, Trovato C, Imarisio M, Talleri D, & Braconi A (2003). Ultrasound assessment of the female perineum: technique, methods, indications and ultrasound anatomy. *Radiologia Medica* **106**, 357-369.

Schaer GN, Koechli OR, Schuessler B, & Haller U (1995). Perineal ultrasound for evaluating the bladder neck in urinary stress incontinence. *Obstetrics & Gynecology* **85**, 220-224.

Schaer GN, Koechli OR, Schuessler B, & Haller U (1996). Perineal ultrasound: determination of reliable examination procedures. *Ultrasound in Obstetrics & Gynecology* **7**, 347-352.

Schuettoff S, Beyersdorff D, Gauruder-Burmester A, & Tunn R (2006). Visibility of the polypropylene tape after tension-free vaginal tape (TVT) procedure in women with stress urinary incontinence: Comparison of introital ultrasound and magnetic resonance imaging in vitro and in vivo. *Ultrasound in Obstetrics and Gynecology* **27**, 687-692.

Shafik A (1998). A new concept of the anatomy of the anal sphincter mechanism and the physiology of defecation: Mass contraction of the pelvic floor muscles. *International Urogynecology Journal and Pelvic Floor Dysfunction* **9**, 28-32.

Shafik A (2000). Neuronal innervation of urethral and anal sphincters: surgical anatomy and clinical implications. [Review] [88 refs]. *Current Opinion in Obstetrics & Gynecology* **12**, 387-398.

Shafik A, Ahmed I, Shafik AA, El-Ghamrawy TA, & El-Sibai O (2005). Surgical anatomy of the perineal muscles and their role in perineal disorders. *Anatomical Science International* **80**, 167-171.

Shafik A, Asaad S, & Doss S (2002). The histomorphologic structure of the levator ani muscle and its functional significance. *International Urogynecology Journal* **13**, 116-124.

Shafik A, Doss S, & Asaad S (2003). Etiology of the resting myoelectric activity of the levator ani muscle: Physioanatomic study with a new theory. *World Journal of Surgery* **27**, 309-314.

Shaw C, Das GR, Williams KS, Assassa RP, & McGrother C (2006). A survey of help-seeking and treatment provision in women with stress urinary incontinence. *BJU International* **97**, 752-757.

Sherburn M, Murphy CA, Carroll S, Allen TJ, & Galea MP (2005). Investigation of transabdominal real-time ultrasound to visualise the muscles of the pelvic floor. *Australian Journal of Physiotherapy 51(3):167-70.*

Siracusano S, Pregazzi R, d'Aloia G, Sartore A, Di BP, Pecorari V, Guaschino S, Pappagallo G, & Belgrano E (2003). Prevalence of urinary incontinence in young and middle-aged women in an Italian urban area. *European Journal of Obstetrics, Gynecology, & Reproductive Biology* **107**, 201-204.

Slieker-ten Hove MCP, Pool-Goudzwaard AL, Eijkemans MJC, Steegers-Theunissen RPM, Burger CW, & Vierhout ME (2008). Face Validity and Reliability of the First Digital Assessment Scheme of Pelvic Floor Muscle Function Conform the New Standardized Terminology of the International Continence Society. *Neurourology & Urodynamics*.

Smith MD, Coppieters MW, & Hodges PW (2007a). Postural activity of the pelvic floor muscles is delayed during rapid arm movements in women with stress urinary incontinence. *International Urogynecology Journal* **18**, 901-911.

Smith MD, Coppieters MW, & Hodges PW (2007b). Postural response of the pelvic floor and abdominal muscles in women with and without incontinence.[see comment]. *Neurourology & Urodynamics* **26**, 377-385.

Smith MD, Russell A, & Hodges PW (2008). Is there a relationship between parity, pregnancy, back pain and incontinence? *International Urogynecology Journal* **19**, 205-211.

Snooks SJ, Swash M, Mathers SE, & Henry MM (1990). Effect of vaginal delivery on the pelvic floor: a 5-year follow-up. *British Journal of Surgery* **77**, 1358-1360.

Sohail S & Siddiqui KJ (2005). Trans-vaginal sonographic evaluation of vesicovaginal fistula. *JPMA - Journal of the Pakistan Medical Association* **55**, 292-294.

Springer BA, Mielcarek BJ, Nesfield TK, & Teyhen DS (2006). Relationships among lateral abdominal muscles, gender, body mass index, and hand dominance. *Journal of Orthopaedic & Sports Physical Therapy* **36**, 289-297.

References

Stokes M, Rankin G, & Newham DJ (2005). Ultrasound imaging of lumbar multifidus muscle: normal reference ranges for measurements and practical guidance on the technique. *Manual Therapy* **10**, 116-126.

Stoylen A. Strain rate imaging. 2008.
Ref Type: Online Source

Streiner DL & Norman GR (1995). Health measurement scales: a practical guide to their development and use. pp. 104-127. Oxford Univeristy Press.

Strohbehn K, Quint LE, Prince MR, Wojno KJ, & DeLancey JO (1996). Magnetic resonance imaging anatomy of the female urethra: a direct histologic comparison. *Obstetrics & Gynecology* **88**, 750-756.

Stuhldreier G, Kirschner HJ, Astfalk W, Schweizer P, Huppert PE, & Grunert T (1997). Three-dimensional endosonography of the pelvic floor: an additional diagnostic tool in surgery for continence problems in children. *European Journal of Pediatric Surgery* **7**, 97-102.

Temml C, Haidinger G, Schmidbauer J, Schatzl G, & Madersbacher S (2000). Urinary incontinence in both sexes: prevalence rates and impact on quality of life and sexual life. *Neurourology & Urodynamics* **19**, 259-271.

Teyhen D (2006). Rehabilitative Ultrasound Imaging Symposium San Antonio, TX, May 8-10, 2006. *Journal of Orthopaedic & Sports Physical Therapy* **36**, A1-A3.

Teyhen DS, Gill NW, Whittaker JL, Henry SM, Hides JA, & Hodges P (2007). Rehabilitative ultrasound imaging of the abdominal muscles. *Journal of Orthopaedic & Sports Physical Therapy* **37**, 450-466.

Theofrastous JP, Wyman JF, Bump RC, McClish DK, Elser DM, Bland DR, & Fantl JA (2002). Effects of pelvic floor muscle training on strength and predictors of response in the treatment of urinary incontinence. *Neurourology & Urodynamics* **21**, 486-490.

Theofrastous JP, Wyman JF, Bump RC, McClish DK, Elser DM, Robinson D, & Fantl JA (1997). Relationship between urethral and vaginal pressures during pelvic muscle contraction. The Continence Program for Women Research Group.[see comment]. *Neurourology & Urodynamics* **16**, 553-558.

Thompson JA & O'Sullivan PB (2003). Levator plate movement during voluntary pelvic floor muscle contraction in subjects with incontinence and prolapse: A cross-sectional study and review. *International Urogynecology Journal and Pelvic Floor Dysfunction* **14**, 84-88.

Thompson JA, O'Sullivan PB, Briffa K, Neumann P, & Court S (2005). Assessment of pelvic floor movement using transabdominal and transperineal ultrasound. *International Urogynecology Journal* **16**, 285-292.

Thompson JA, O'Sullivan PB, Briffa NK, & Neumann P (2006a). Altered muscle activation patterns in symptomatic women during pelvic floor muscle contraction and Valsalva manouevre. *Neurourology & Urodynamics* **25**, 268-276.

Thompson JA, O'Sullivan PB, Briffa NK, & Neumann P (2006b). Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze pressure measurements. *International Urogynecology Journal* **17**, 624-630.

Thompson JA, O'Sullivan PB, Briffa NK, & Neumann P (2007). Comparison of transperineal and transabdominal ultrasound in the assessment of voluntary pelvic floor muscle contractions and functional manoeuvres in continent and incontinent women. *International Urogynecology Journal* **18**, 779-786.

Thyer I, Shek C, & Dietz HP (2008). New imaging method for assessing pelvic floor biomechanics. *Ultrasound in Obstetrics & Gynecology* **31**, 201-205.

Toozs-Hobson P, Balmforth J, Cardozo L, Khullar V, & Athanasiou S (2008). The effect of mode of delivery on pelvic floor functional anatomy. *International Urogynecology Journal* **19**, 407-416.

Toozs-Hobson P, Khullar V, & Cardozo L (2001). Three-dimensional ultrasound: A novel technique for investigating the urethral sphincter in the third trimester of pregnancy. *Ultrasound in Obstetrics and Gynecology* **17**, 421-424.

Troyano J, Clavijo M, Gonzalez-Lorenzo A, Martinez-Wallin I, Marco O, Casas P, Martinez-Cortes L, Merce L, Bajo-Arenas J, Hernandez N, & Castro D (2006). Female pelvic floor. Descriptive anatomy and clinical exploration by transvaginal ultrasound. *Ultrasound Review of Obstetrics and Gynecology* **6**, 79-99.

Tunn R, Gauruder-Burmester A, & Kolle D (2004). Ultrasound diagnosis of intra-urethral tension-free vaginal tape (TVT) position as a cause of postoperative voiding dysfunction and retropubic pain. *Ultrasound in Obstetrics & Gynecology* **23**, 298-301.

Tunn R, Schaer G, Peschers U, Bader W, Gauruder A, Hanzal E, Koelbl H, Koelle D, Perucchini D, Petri E, Riss P, Schuessler B, & Viereck V (2005). Updated recommendations on ultrasonography in urogynecology. *International Urogynecology Journal 16(3):236-41,* -Jun.

Turker KS (1993). Electromyography: some methodological problems and issues. *PHYS THER* **73**, 698-710.

Umek WH, Laml T, Stutterecker D, Obermair A, Leodolter S, & Hanzal E (2002). The urethra during pelvic floor contraction: observations on three-dimensional ultrasound. *Obstetrics & Gynecology* **100**, 796-800.

Umek WH, Obermair A, Stutterecker D, Hausler G, Leodolter S, & Hanzal E (2001). Three-dimensional ultrasound of the female urethra: comparing transvaginal and transrectal scanning. *Ultrasound in Obstetrics & Gynecology* **17**, 425-430.

Uyar Y, Baytur YB, & Inceboz U (2007). Perineometer and digital examination for assessment of pelvic floor strength. *International Journal of Gynecology & Obstetrics* **98**, 64-65.

van Loenen NT & Vierhout ME (1997). Augmentation of urethral pressure profile by voluntary pelvic floor contraction. *International Urogynecology Journal* **8**, 284-287.

Vasseljen O, Dahl HH, Mork PJ, & Torp HG (2006). Muscle activity onset in the lumbar multifidus muscle recorded simultaneously by ultrasound imaging and intramuscular electromyography. *Clinical Biomechanics* **21**, 905-913.

Vasseljen O, Fladmark AM, Westad C, & Torp HG (2009). Onset in abdominal muscles recorded simultaneously by ultrasound imaging and intramuscular electromyography. *Journal of Electromyography & Kinesiology* **19**, e23-e31.

Verelst M & Leivseth G (2004a). Are fatigue and disturbances in pre-programmed activity of pelvic floor muscles associated with female stress urinary incontinence? *Neurourology & Urodynamics* **23**, 143-147.

Verelst M & Leivseth G (2004b). Force-length relationship in the pelvic floor muscles under transverse vaginal distension: a method study in healthy women. *Neurourology & Urodynamics* **23**, 662-667.

Verelst M & Leivseth G (2007). Force and stiffness of the pelvic floor as function of muscle length: A comparison between women with and without stress urinary incontinence. *Neurourology & Urodynamics* **26**, 852-857.

Verhey JF, Wisser J, Warfield SK, Rexilius J, & Kikinis R (2005). Non-rigid registration of a 3D ultrasound and a MR image data set of the female pelvic floor using a biomechanical model. *Biomedical Engineering Online* **4**, 19.

Viereck V, Bader W, Krauss T, Oppermann M, Gauruder-Burmester A, Hilgers R, Hackenberg R, Hatzmann W, & Emons G (2005). Intra-operative introital ultrasound in Burch colposuspension reduces post-operative complications. *BJOG: An International Journal of Obstetrics and Gynaecology* **112**, 791-796.

Viereck V, Bader W, Skala C, Gauruder-Burmester A, Emons G, Hilgers R, & Krauss T (2004). Determination of bladder neck position by intraoperative introital ultrasound in colposuspension: outcome at 6-month follow-up. *Ultrasound in Obstetrics & Gynecology* **24**, 186-191.

Viereck V, Pauer HU, Hesse O, Bader W, Tunn R, Lange R, Hilgers R, & Emons G (2006). Urethral hypermobility after anti-incontinence surgery - a prognostic indicator? *International Urogynecology Journal* **17**, 586-592.

Viktrup L, Rortveit G, & Lose G (2006). Risk of stress urinary incontinence twelve years after the first pregnancy and delivery.[see comment]. *Obstetrics & Gynecology* **108**, 248-254.

Weinstein MM, Jung SA, Pretorius DH, Nager CW, den Boer DJ, & Mittal RK (2007). The reliability of puborectalis muscle measurements with 3-dimensional ultrasound imaging. *American Journal of Obstetrics & Gynecology* **197**, 68-6.

Weinstein MM, Pretorius DH, Jung SA, Nager CW, & Mittal RK (2009). Transperineal three-dimensional ultrasound imaging for detection of anatomic defects in the anal sphincter complex muscles. *Clinical Gastroenterology & Hepatology* **7**, 205-211.

Whelan M (2008). Patient Assessment, Vaginal Palpation. In *Therapeutic Management of Incontinence and Pelvic Pain*, eds. Laycock J & Haslam J, pp. 60-61. Springer.

White RD, McQuown D, McCarthy TA, & Ostergard DR (1980). Real-time ultrasonography in the evaluation of urinary stress incontinence. *American Journal of Obstetrics & Gynecology* **138**, 235-237.

Whittaker JL (2007). *Ultrasound Imaging for Rehabilitation of the Lumbopelvic Region: A Clinical Approach* Elsevier Churchill Livingstone, Edinburgh, UK.

Whittaker JL, Teyhen DS, Elliott JM, Cook K, Langevin HM, Dahl HH, & Stokes M (2007a). Rehabilitative ultrasound imaging: understanding the technology and its applications. *Journal of Orthopaedic & Sports Physical Therapy* **37**, 434-449.

Whittaker JL, Thompson JA, Teyhen DS, & Hodges P (2007b). Rehabilitative ultrasound imaging of pelvic floor muscle function. *Journal of Orthopaedic & Sports Physical Therapy* **37**, 487-498.

Wijma J, Tinga DJ, & Visser GH (1991). Perineal ultrasonography in women with stress incontinence and controls: the role of the pelvic floor muscles. *Gynecologic & Obstetric Investigation* **32**, 176-179.

Wilson P, Herbison G., & Heer K (1991). Reproducibility of perineometry measurements. *Neurourology & Urodynamics* **10**, 399-400.

Wise BG, Burton G, Cutner A, & Cardozo LD (1992). Effect of vaginal ultrasound probe on lower urinary tract function.[see comment]. *British Journal of Urology* **70**, 12-16.

Wisser J, Schar G, Kurmanavicius J, Huch R, & Huch A (1999). Use of 3D ultrasound as a new approach to assess obstetrical trauma to the pelvic floor. *Ultraschall in der Medizin* **20**, 15-18.

Wyman JF, Fantl JA, McClish DK, & Bump RC (1998). Comparative efficacy of behavioral interventions in the management of female urinary incontinence. Continence Program for Women Research Group. *American Journal of Obstetrics & Gynecology* **179**, 999-1007.

Yalcin OT, Hassa H, & Tanir M (2002). A new ultrasonographic method for evaluation of the results of anti-incontinence operations. *Acta Obstetricia et Gynecologica Scandinavica* **81**, 151-156.

Yang SH, Huang WC, Yang SY, Yang E, & Yang JM (2009). Validation of new ultrasound parameters for quantifying pelvic floor muscle contraction. *Ultrasound in Obstetrics & Gynecology* **33**, 465-471.