

DEVELOPMENT OF A PAD TEST TO ASSESS STRESS URINARY INCONTINENCE IN
YOUNG HEALTHY WOMEN: A PILOT STUDY

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By

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ABSTRACT

Purpose: Current literature reports that between 7 and 14% of young, healthy women have stress urinary incontinence (SUI). No gold standard exists for quantifying urine leakage, although pad tests have been used in older, parous populations. The aim of this study was to determine the reliability and accuracy of a new pad test for young, healthy women with SUI. **Methods:** The pad test consisted of measuring quantity of leakage after the following activities: stair running, standing up from sitting, curl-ups, running on the spot, jumping jacks, jumping on a mini-trampoline and coughing vigorously. Bladder volume was standardised by having the volunteers drink one litre of water one hour prior to the testing. The volunteers performed the pad test on two consecutive days. **Results:** Sixteen nulliparous women between the ages of 18 and 30 years (7 controls and 9 with SUI) participated in this study. The mean increase in pad weight was 0.64 g (± 0.50) in the continent group and 11.89 g (± 20.32) in the group with SUI. There was no significant difference in pad weight between the testing sessions ($p=0.228$), however the test was not able to elicit measureable urine loss in 3 participants with SUI. Pad weights between the two groups of women were significantly different ($p=0.023$). The test re-test ICC for the continent group was 0.845 (95% CI: 0.139–0.973) and 0.782 (95% CI: -0.040–0.952) for the group with SUI. **Significance:** The results of this study support the use of this pad test in healthy young women with SUI; it appears to be reliable and challenging enough to cause measureable urine loss in the majority, and it may be useful for diagnosing and quantifying SUI without urodynamic studies.

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CHAPTER 1 INTRODUCTION

Urinary incontinence (UI), defined by the International Continence Society as “any involuntary leakage of urine,”¹ is experienced by at least 50% of women at some time in their lives.² There are several types of UI, the most prevalent is stress urinary incontinence (SUI):^{3,4} defined as “any leakage on effort or exertion, or on sneezing or coughing.”¹

SUI in young, healthy, nulliparous women was first reported in the literature in 1954. Nemir and Middleton⁵ found that 695 of 1,327 (52.4%) female, nulliparous university students between the ages of 17 and 21 years reported via questionnaire to occasional (49.7%) or frequent (2.6%) SUI. In 1969, Wolin reported similar results with a sample of 4,211 nulliparous nursing students between the ages of 17 and 25 years. He found that 2,135 (50.7%) had some degree of SUI, with 1,451 (34.5%) experiencing occasional and 684 (16.2%) experiencing daily leakage.⁶ More recent studies have reported prevalences of SUI in young women that range between 3.7% and 14%.^{4,7-12} The prevalence of SUI in physically active young women rises to 49% in college athletes¹³ and 19-31%¹⁴⁻¹⁷ of women in military training or in the armed forces.

The negative effects of UI on quality of life have been widely reported in the literature;^{3,12,18-23} however the majority of the studies do not differentiate between types of UI. Social, work and sexual activities can all be affected by UI.^{18,22,24,25} Women with UI may limit their social lives by avoiding leaving the house for long periods,²⁰ considering quitting their sport,²¹ restricting their activities, including work, and limiting fluid intake to prevent leakage.^{12,19,22} Younger women with UI demonstrate greater activity restrictions than do older women with the same UI severity.^{19,22} In a study assessing the impact of UI on the sex lives of women and their partners, 22% of men and 43% of women stated that the woman’s urinary problems impaired their sexual life.²⁴ Forty-nine percent of the women worried about leaking during sexual activity and 14% thought that their ability to reach orgasm had decreased secondary to UI.

Higher rates of anxiety and depression in women with UI have been well-documented.^{3,12,19,22,26-28} Young women with UI have lower psychological well-being than those without leakage.¹² Sixteen percent of women with UI under the age of 30 consider their urinary leakage to be extremely embarrassing or humiliating,²⁰ and half of young, nulliparous women with UI between the ages of 16 and 30 worry about odour.¹² In a Canadian study, the prevalence of major depression in women with UI (15.5%) was significantly greater than in women without

UI (9.2%), with an odds ratio of 5.73 (95% CI: 3.11-10.54) for having major depression in the presence of UI.²⁶ This association was found to be even stronger in the youngest age-group (18-44 years), a finding that has been supported by the literature.^{19,22} In addition, the percentage of Canadian women with UI and depression expressing excellent general health (15.1%) was significantly lower than those with only UI (59.2%).²⁶ The percentage who reported being “quite a bit” or “extremely” stressed (Health Utility Index, Mark III) was also significantly different between the two groups (61.6% of women with comorbid UI and depression versus 26.6% of women with UI who were not depressed). Taken together, this research suggests that UI can lead to behavioural, psychological and health concerns, far beyond the symptom of the urine leakage itself.

1.1 Aetiology of SUI in Young Women

To maintain continence, urethral closure pressure must be greater than bladder pressure, both at rest and with activity, and independent of the volume of urine in the bladder.²⁹ It is well-established that the endopelvic fascia (connective tissue), pelvic floor muscles (PFMs), striated urethral sphincter and neuromuscular control all contribute to the continence mechanism.^{29,30} This system is disrupted in women with SUI, but the mechanisms behind the disruption are not well understood. It has been widely assumed that SUI develops as the result of trauma sustained during vaginal delivery.^{9,11,31,32} Indeed, elective Caesarian sections are now being performed with the sole purpose of avoiding incontinence.³³ However, this does not explain the common occurrence of SUI in young, nulliparous women,⁴⁻¹¹ and there is little research in this population.

Factors associated with SUI in young, nulliparous women include increased body mass index (BMI),^{32,34,35} high impact physical activity,^{13-17,34,36-39} oral contraceptive use,^{40,41} sexual activity,¹² smoking,^{11,35,42,43} a history of urinary tract infections (UTIs),^{10,32} and chronic constipation.^{9,32,44} Genetic traits, such as connective tissue composition, have also been suggested as potential factors.^{16,45-48} Currently, the most robust models based on studies of twins suggest that SUI in young women is the result of equal parts genetic predisposition and environmental factors.⁴⁹

1.2 Measurement

Given the high prevalence and the frequently negative implications of SUI in young women, it is essential for both clinicians and researchers to have methods to objectively measure urine loss in this population in order to effectively assess and manage the condition. Leakage

severity has been quantified in five different ways: with patient-reported outcome (PRO) questionnaires, bladder diaries, urodynamic testing, cough stress tests, and pad tests.^{50,51}

PRO questionnaires and bladder diaries are used to record the individual's perception of their urine leakage, but the tools are not able to measure the quantity of urine lost and individuals' estimates of leakage volume will be subjective.⁵¹ In addition, some have been shown to be inapplicable for women who have not been diagnosed using urodynamics.⁵² There is also disagreement in the perceived value of PROs, with some suggesting that they are no better than a clinical history,⁵³ and others arguing that they offer a complementary and independent role in a comprehensive assessment for SUI.⁵⁴ While bladder diaries are used extensively in the literature, to date no diary has been scientifically validated. Some argue that a diary provides no more information than a clinical history,⁵⁵ but others suggest that if a diary has been correctly completed, it can reduce recall bias.⁵⁶

Urodynamic testing and cough stress testing are both done in the specialist's office and involve the artificial filling of the bladder via a catheter. Urodynamic testing is an invasive functional study of the lower urinary tract, requiring the insertion of catheters into the urethra, bladder and rectum.^{50,57} It is used to diagnose a variety for lower urinary tract disorders, including SUI. A cough stress test is a simple test to assess for SUI. It requires the woman to cough forcefully with a full bladder, while the investigator or clinician watches for urine leakage from the urethra.⁵⁸⁻⁶⁰ Both tests permit the clinician or researcher to observe whether urine leakage occurs under certain conditions;^{50,51} however, the amount of leakage can only be measured with the modified cough stress test (paper towel test).^{59,61} Urodynamics are expensive,⁶² and many of the parameters have yet to be properly standardised, are poorly reproducible, and are not able to contribute to the differential diagnosis or to detect minimally important changes.⁶²⁻⁶⁶ The International Continence Society recommends that such invasive studies are not necessary when the type of UI is clear and the planned treatment is reversible.⁵⁰ Cough stress tests are simple to use but do not correlate well with patient-reported symptoms,⁶⁷ and patients find these tests to be embarrassing to perform.⁶⁸

The objective of pad testing is to quantify the volume of urine lost by weighing an absorbent pad before and after some type of leakage provocation.⁶⁹ Only pad tests are able to quantify the volume of urine lost during activity. There are two types of pad test: home-based and office-based. The home-based tests serve to assess urinary leakage while the woman

performs her daily activities, and typically takes place over 24 to 48 hours. The office-based pad test, on the other hand, involves the participant performing standardised physical activities in a clinical setting for a period up to one hour.⁵¹ Office-based pad tests are inexpensive, non-invasive, can be standardised, and are reproducible.⁷⁰ Although SUI is prevalent in young, healthy women, the pad tests that have been reported in the literature have been developed for and validated in the older, parous population.⁷¹⁻⁸⁰

Each of the five methods for assessing leakage severity has problems with reliability and validity so, to date, there is no gold standard for measuring the severity of SUI or changes in leakage with treatment.⁵³

1.3 Purpose

It has been established that reliable, repeatable means of evaluating urinary incontinence are required to objectively assess and treat women with SUI. With health care costs soaring world wide, clinicians are seeking inexpensive assessment tools that can be used in a primary care setting.⁵³ The World Health Organization and the International Continence Society recommend pad testing as a method to detect and quantify urine loss.⁵¹ Our preliminary study, based on pad tests from two research studies that included women under the age of 30,^{81,82} revealed that these tests were not provocative enough to elicit urine loss in young, nulliparous women with SUI (Appendix A). In order to adequately quantify SUI in women between the ages of 18 and 30 years, a new test, one more provocative than other pad tests, is required. The purpose of this pilot study was to determine the reliability of a new, standardised pad test designed specifically to assess urine leakage in young, healthy women with SUI.

1.4 Hypothesis

It was hypothesized that this new pad test would demonstrate good reliability⁸³ and accuracy in young, healthy women with and without SUI between the ages of 18 and 30 years.

CHAPTER 2 LITERATURE REVIEW

In order to fully understand the complicated nature of SUI and to be able to assess it properly, it is necessary to first examine the normal anatomy and physiology of the continence system. Then, exploring the aetiology of SUI will reveal the many potential deficits in the continence mechanism. The examination of the environmental and familial risk factors for SUI in young, nulliparous women will further the understanding of how SUI might develop in this population. Finally, discussing the various methods currently available to measure the symptoms of SUI will provide the background for the development of a new pad test for healthy women between the ages of 18 and 30 years.

2.1 Lower Urinary Tract Anatomy and Physiology

2.1.1 Bladder

The main function of the lower urinary tract is to store and excrete urine. Urine is continuously excreted from the kidneys and is delivered to the bladder via the ureters. The bladder stores the urine until there is a convenient, socially appropriate time and place to evacuate. The bladder outlet is in the inferior corner of the bladder and is comprised of the bladder neck, urethra and urethral sphincter (Figure 2.1).

2.1.1.1 Bladder anatomy

The bladder is a multi-layered hollow sack whose walls are made up of four layers: the urothelium or lining, the lamina propria, the detrusor and the outer serosal layer.⁸³ The urothelium is essentially water-tight, having a very low permeability to urine and pathogens.⁸³ The lamina propria is comprised of collagen and elastin, which affects passive wall tension.⁸³ The detrusor is smooth muscle making up 60-70% of the bladder wall thickness, with muscle cells arranged in longitudinal and circumferential layers, varying in orientation and thickness.^{83,84} During filling the detrusor is relaxed, and with micturition it contracts to push the urine out through the urethra.⁸⁵ The outer serosal layer, comprised of mesothelium and connective tissue, is part of the peritoneum and covers the superior aspect of the bladder.⁸⁴

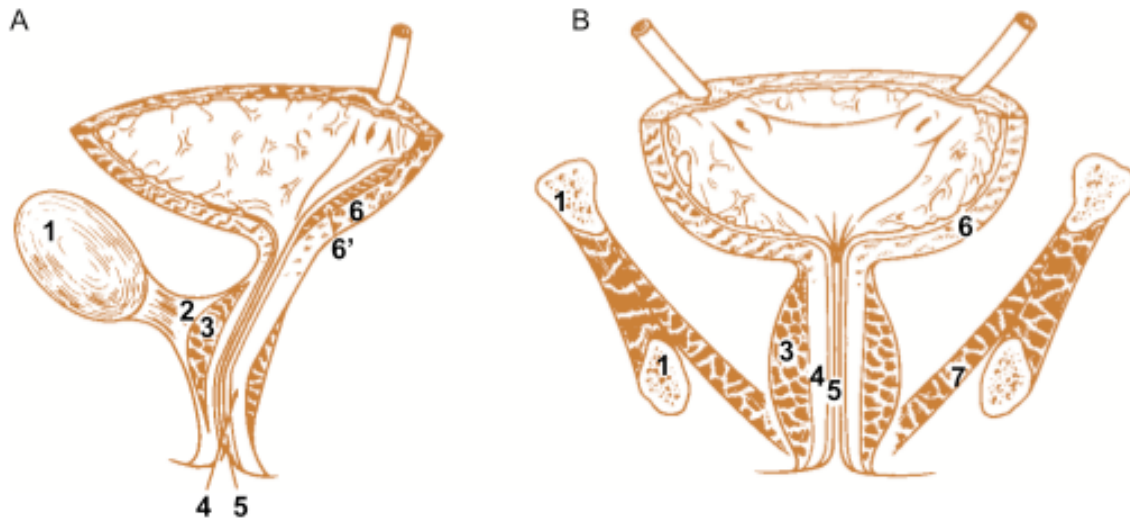


Figure 2.1: Schematic diagrams of female bladder and urethra in sagittal section (A) and coronal section (B).

(1) Pubic symphysis/rami; (2) posterior pubo-urethral ligaments; (3) intrinsic striated muscle; (4) intrinsic smooth muscle; (5) mucosa and submucosal vascular tissues; (6) smooth muscle of detrusor/deep trigone; (6') smooth muscle of superficial trigone (7) extrinsic striated muscle/levator ani. From: Keane, D. P. and S. O'Sullivan (2000). "Urinary incontinence: anatomy, physiology and pathophysiology." *Best Practice Research Clinical Obstetrics & Gynaecology* 14(2): 207-226.

The trigone, the triangular area that forms the base of the bladder, differs in embryological origin from the rest of the bladder and is the only area of the bladder in which this basic structure differs.⁸⁶ Its three corners are comprised of the two ureteric openings superiorly through which the urine arrives from the kidneys, and the urethra inferiorly through which urine is expelled.⁸⁴ Trigonal muscular composition differs from that of the detrusor by having smaller myocytes in smaller muscle bundles and a greater percentage of connective tissue. The trigonal muscle is continuous with the smooth muscle of the ureters and the urethra, and is backed by the outer longitudinal and middle circular smooth muscle layers of the detrusor.^{83,84}

The trigone plays a crucial role in bladder filling, continence and micturition. The continuity of smooth muscle from the ureters with the trigone helps to prevent urinary reflux into the ureters.^{83,86} Muscarinic receptors in the trigone may also help to prevent urinary reflux into the ureters during involuntary detrusor contractions by facilitating a synergistic mechanism that produces an even stronger contraction of the interureteric muscle.⁸³ During the filling phase, the trigone receives input from the sympathetic nervous system that stimulates the trigonal and internal urethral smooth muscle to contract, via alpha-adrenergic receptors, in order to keep the internal urethral opening closed and maintain continence.^{83,86} During micturition, the trigone acts

as a stable structure on which the dome of the bladder can contract; it is also believed to relax and cause a funneling of the bladder base into the urethra to facilitate voiding.⁸³

2.1.1.2 Neurological control

The bladder differs from other visceral structures in a two ways. First, unlike cardiovascular organs, which have a tonic pattern of activity, the bladder functions under phasic control with only two modes: storage and elimination. Second and most significantly, bladder control is a learned behaviour, necessitating maturation of the nervous system, whereas other organs are regulated involuntarily.⁸⁷

Due to voluntary control of micturition, the storage and periodic emptying of urine is controlled by a complex neural system located in the brain, spinal cord and peripheral ganglia.⁸⁷ Storage reflexes occur primarily at the level of the spinal cord, whereas voluntary micturition is organized within the brain. Neurons in the pontine micturition centre, periaqueductal grey, caudal and preoptic hypothalamus and several parts of the cerebral cortex, especially the medial frontal cortex are all involved in the control of the bladder, urethra and urethral sphincter.⁸⁷

The pelvic plexus contains both parasympathetic and sympathetic innervation to the bladder. The parasympathetic innervation primarily controls the voiding stage and its motor nerves originate from the anterior sacral roots of S₂-S₄ and course through the pelvic splanchnic nerves. Parasympathetic postganglionic nerves release both acetylcholine and non-adrenergic, non-cholinergic neurotransmitters. Cholinergic transmission serves to initiate the contraction of the detrusor muscle, allowing voiding to occur. Non-cholinergic contraction is mediated by ATP in the detrusor muscle. Urethral and trigonal smooth muscle inhibition is mediated by nitric oxide, released by the parasympathetic nerves, permitting relaxation of the smooth muscle to assist with bladder emptying.^{83,87} The sympathetic system is primarily responsible for urine storage, with fibres from T₁₀-L₂ travelling through the superior hypogastric plexus to the pelvic plexus.^{84,86-88} Sympathetic postganglionic nerves release noradrenaline, activating β -adrenergic inhibitory receptors in the detrusor muscle to relax the bladder. They also have an excitatory effect on α -adrenergic receptors in the urethra and bladder neck causing them to contract, thus facilitating urine storage.^{83,87}

Sensory information from the bladder is also transmitted by the autonomic nervous system. Sacral visceral afferent fibres are distributed in the detrusor muscle and submucosa, allowing the sensations of touch, pain and bladder filling to be interpreted by the brain.⁸⁶ Sensations of

bladder distension are conveyed to the spinal cord via the pelvic and hypogastric nerves, whereas sensory input from the bladder neck travels along the pudendal and hypogastric nerves.⁸⁷ A sensory plexus within the suburothelial layer, which is more prominent at the bladder neck and quite sparse at the dome of the bladder, is believed to convey the sensory information from the urothelium. In addition, non-neuronal sensory cells in the urothelium possess signaling properties that permit the response to chemical and mechanical stimuli. These cells are able to communicate reciprocally with the nerves within the bladder wall.⁸⁷

2.1.2 The Continence Mechanism

The continence mechanism is divided into intrinsic and extrinsic components. The intrinsic portion is comprised of the urethra: with an inner mucosa, vascular plexus, and smooth muscle layers, and the surrounding striated urethral sphincters,⁸⁹ all of which contribute equally to resting urethral closure pressure.^{29,90} The extrinsic mechanism is made up of the pelvic floor muscles (PFMs) and fascial supports.^{90,91} This mechanism serves to close the urethral, vaginal and rectal openings, as well as to support the pelvic organs.^{29,92,93}

2.1.2.1 Intrinsic mechanism

The urethra passes from the bladder base, through the PFMs, until it emerges onto the perineum, ventral to the vaginal opening. The urethral lumen is surrounded by epithelium and possesses a substantial vascular bed within the submucosa (Figure 2.2). The vascular plexus contributes to coaptation, forming a hermetic seal.^{29,85,86,91} Beyond the submucosa lie two layers of smooth muscle: an inner longitudinal layer and an outer circular layer. The function of the longitudinal smooth muscle is not known, but has been hypothesized to shorten the urethra⁸³ and assist with opening the lumen during micturition.²⁹ The outer circular layer occludes the lumen to assist with urine storage.^{29,83,84} As the urethra passes through the bladder neck, the detrusor muscle fibres travel along it for the first 15%, forming a U-shaped loop around the urethra that creates an internal sphincter and assists with closure.²⁹ While present in all men, this sphincter is absent in many women.⁹⁴ As in the bladder, the urethral sphincter system is innervated by the autonomic nervous system, originating in the pelvic plexus.⁸⁹ The sympathetic fibres contract the smooth muscles of the urethra, inhibiting urine outflow.^{83,86,88} To allow micturition, parasympathetic nerve fibres relax the urethral smooth muscles, especially in the proximal portion.⁸⁸

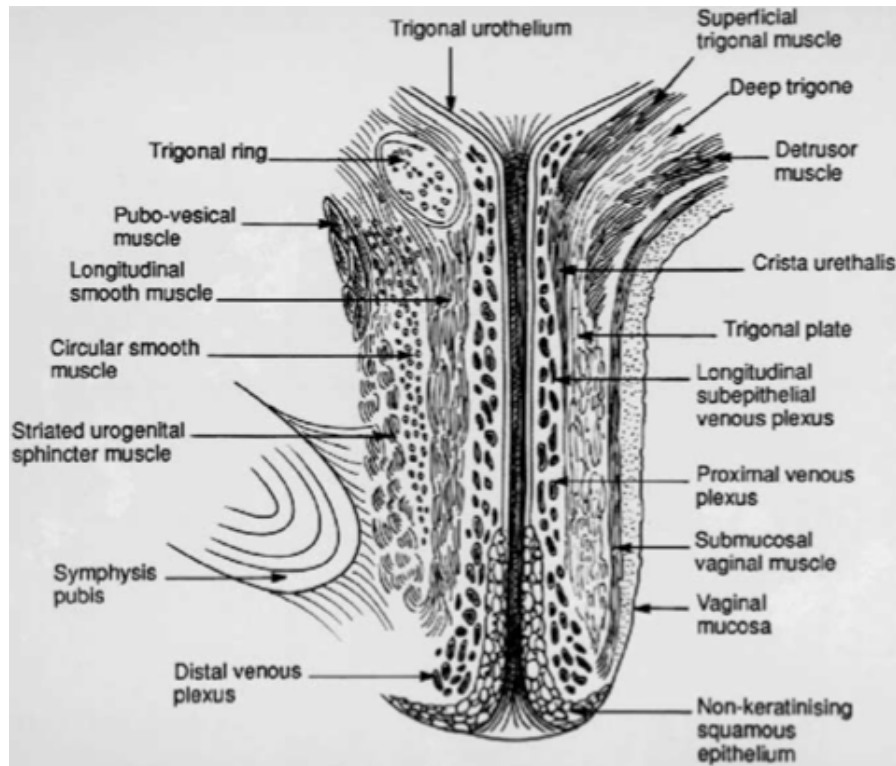


Figure 2.2: Midsagittal section through the urethra.

From: Ashton-Miller, J. A. and J. O. L. DeLancey (2007). *Functional Anatomy of the Female Pelvic Floor*. Annals of the New York Academy of Sciences 1101(1): 266-296. (©Delancey, 1997)

The circular fibres of the striated urethral sphincter begin where the detrusor muscle fibres end and extend down the middle third of the urethra.²⁹ The striated sphincter is innervated by the perineal branches of the pudendal nerve (S₂ to S₄) and is comprised primarily of slow-twitch fibres, these produce constant tone to maintain continence and phasic increases in contraction force as required, to resist increases in intra-abdominal pressure.^{86,95}

Halfway down the urethra, the striated muscles of the urogenital diaphragm, the compressor urethrae and the urethrovaginal sphincter, start.^{29,85} Although they are continuous with the striated urethral sphincter fibres,⁸⁹ they are not circular, but rather omega-shaped.^{96,97} The fibres of the compressor urethrae ultimately attach to connective tissue next to the perineal membrane bilaterally, near the inferior pubic rami. As its name suggests, the urethrovaginal sphincter surrounds both the urethra and the vagina.^{29,90} Contraction of these two muscles compresses the lumen of the urethra against the anterior vaginal wall.²⁹ Small nerves running off the terminal branch of the pudendal nerve innervate the compressor urethrae and the urethrovaginal sphincter.⁹⁶

2.1.2.2 Extrinsic mechanism

Support for the urethra (Figure 2.3) is derived posteriorly and inferiorly from the anterior vaginal wall,^{29,30} the endopelvic fascia, the arcus tendinous fasciae pelvis (ATFP) and the pelvic floor muscles (PFMs).^{29,88,90} The endopelvic fascia is a thick, fibrous layer of connective tissue that surrounds the vagina and the ATFP laterally.^{29,90} This fascia contains collagen, a high concentration of elastin and, unlike other fascia within the body, it also contains smooth muscle fibres.^{93,98} Each ATFP attaches to the pubic bone ventrally and the ischial spine dorsally. They are tensile structures that suspend the anterior vaginal wall, and through it the urethra, from the pelvis,^{29,90} preventing both the vagina and the urethra from moving inferiorly and posteriorly.⁹⁹

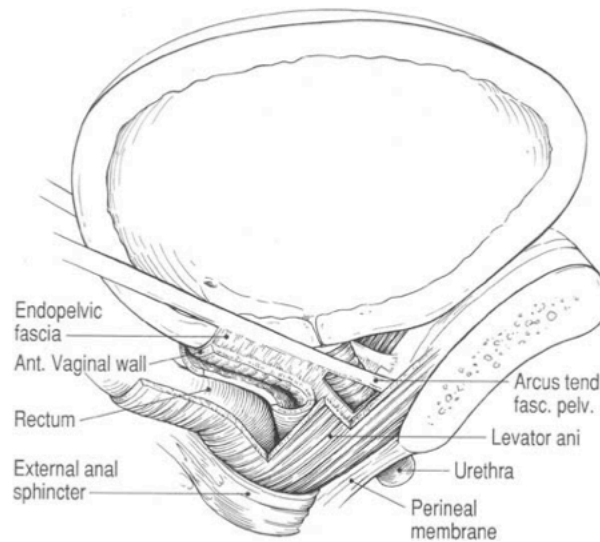


Figure 2.3: Sagittal section of the components of the urethral support system.

From: Delancey, J. O. L. and J. A. Ashton-Miller (2004). Pathophysiology of adult urinary incontinence. *Gastroenterology* 126, Supplement 1(0): S23-S32. (© Delancey 2005)

The PFMs are striated muscles within the pelvis, made up of the pubovisceral, iliococcygeus (which together form the levator ani) and ischiococcygeus (coccygeus) muscles (Figure 2.4).^{93,100} The pubovisceral muscles are comprised of puborectal and pubococcygeal components, and originate from both the left and right ventral pubic bones. Each pubovisceral muscle curves posteriorly and inferiorly past the urethra, vagina and anorectum to attach to its contralateral half behind the rectum and inserts into the anal sphincter complex and the anococcygeal raphe.^{93,100} Together they form a U-shaped sling of muscle that maintains constant tone to keep the urogenital hiatus closed, relaxing only during micturition and defaecation.^{90,101} The central space

through which the anus, vagina and urethra pass is called the urogenital hiatus; it is supported ventrally by the pubic bones, laterally by the PFMs and dorsally by the perineal body and external anal sphincter.^{85,93}

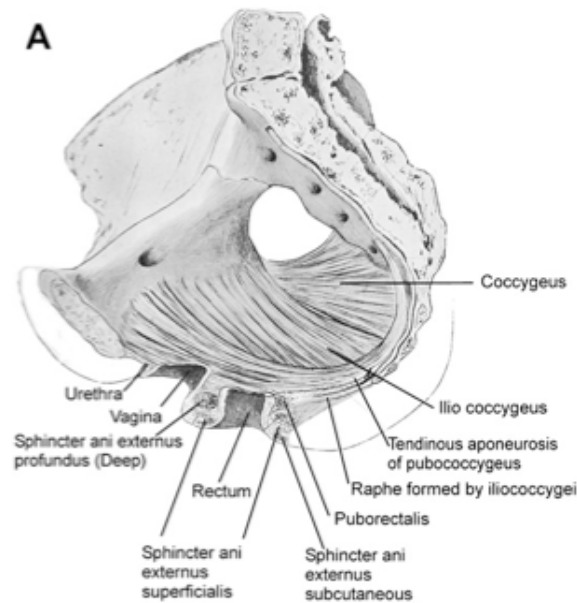


Figure 2.4: Pelvic floor muscles in sagittal section of the pelvis.

From: Raizada, V. and R. K. Mittal (2008). "Pelvic Floor Anatomy and Applied Physiology." *Gastroenterology Clinics* 37(3): 493-509.

The iliococcygeus forms a flat sheet that runs from the pelvic sidewall to the midline, originating at the arcus tendinous levator ani (ATLA) bilaterally. The ATLA is a thickened portion of the fascia that overlies the medial aspect of the obturator internus (OI) muscle, originating on the posterior aspect of the pubis and inserting on the ischial spine.^{99,100} The ATLA suspend the pubococcygeus and puborectalis muscles anteriorly and they anchor the iliococcygeus to the pelvic sidewall;⁹⁹ ensuring that the PFMs function independently of the OI, regardless of the state of OI contraction or relaxation.⁹⁰ From the ATLA, the iliococcygeus traverses posteriorly, medially and obliquely downward, inserting on the coccyx and anococcygeal raphé, opposite its contralateral partner.¹⁰⁰ The anterior fibres of the iliococcygeus run medially and caudally, while the posterior fibres are more horizontally-oriented, providing a shelf to support the pelvic organs.^{29,90,92,93,100} The ischiococcygeus muscle overlies the

sacrospinous ligament, originating from the pelvic surface of the ischial spine, and attaching to the lateral aspect of the coccyx and distal sacrum.¹⁰⁰

Innervation of the PFMs is highly variable. The perineal and inferior rectal branches of the pudendal nerve (S₂ to S₄),^{102,103} as well as direct sacral nerves from S₃ through S₅,^{88,102-105} have been most commonly reported. A variant of the inferior rectal nerve (S₃ and/or S₄) which is independent of the pudendal nerve has also been found to innervate the PFMs directly.¹⁰²

The PFMs are comprised primarily (70%) of type I (slow twitch) striated muscle fibres,^{90,101} but they also contain smooth muscle fibres that increase in number medially and eventually split into their own layer of muscle.¹⁰⁶ It is hypothesized that the smooth muscle fibres may be responsible for the resting electromyographic activity in the PFMs and that these fibres are likely responsible for the change in PFM tone in response to visceral weight and gradual changes in intra-abdominal pressure (IAP).^{104,106}

Although the PFMs are composed of three pairs of anatomically distinct muscles, there is no evidence to suggest that they can be activated independently, but rather that contraction produces a collective compound action that is the product of the various muscle fibre directions. Contraction of the pubococcygeus, iliococcygeus and ischiococcygeus results in flexion of the coccyx ventrocranially and elevation of the PFMs themselves, thus providing mechanical support for and lifting of the pelvic viscera in a cephalic direction.¹⁰⁷⁻¹¹⁰ Contraction of the puborectalis results in a decrease in levator hiatus area and compression of the urethra,¹¹¹ vagina and rectum in an anterior direction against the pubic bone.^{93,107} These closure and support functions of the PFMs also protect the connective tissue within the pelvis from stretching.^{29,85,92,99}

2.1.2.3 Physiology

To maintain continence, urethral closure pressure must exceed bladder pressure, both at rest and with increases in IAP.^{90,112} In healthy women, the resting tone of the urethral smooth muscles and the striated sphincter complex, and the passive force from the vascular plexus, ensure that the urethral pressure is higher than the bladder pressure at rest.^{29,90} As the bladder fills, contraction of the PFMs is thought to assist with generating sufficient urethral closure pressure. With activities that increase IAP, such as coughing or lifting, both active and passive components contribute to enhancing urethral closure and maintaining continence.^{29,112-115} In healthy women, when IAP increases, the striated urethral sphincter contracts to close the proximal urethral lumen. PFM contraction stabilizes the bladder neck; limits the descent of the

urethra, preventing it from being stretched open; and increases pressure within the distal portion of the urethra.^{114,116} The increasing IAP passively compresses the bladder neck and proximal urethra against the endopelvic fascia, the ATPF, the PFMs and the anterior vaginal wall.^{90,114-116} Contraction of the PFMs also assists with this passive action by increasing the stiffness of the supportive layer by pretensioning the endopelvic fascia and vaginal wall tissues, providing a backstop against which the abdominal pressure compresses the urethra.^{90,98,116} Through these actions, the PFMs also protect the connective tissue from undue stress.

In addition to luminal closure and pelvic organ support, the PFMs have been shown to be active with quiet breathing, and involved in the anticipatory postural adjustments associated with postural perturbations, such as arm movements, leg lifts and catching a weight.¹¹⁵⁻¹¹⁷ Recent evidence also indicates that the PFMs assist, not only with maintaining continence during forced expiration, such as a cough,¹¹⁸ but also in improving the efficacy of the expiratory effort.¹¹⁹ Thus, it is clear that the PFMs play multiple roles in maintaining continence, improving postural stability and expiratory effort, and that injury to the PFMs may have multiple, overlapping consequences.

2.2 Aetiology of SUI in Young, Nulliparous Women

Stress urinary incontinence (SUI) seems to be produced by overlapping deficits in multiple components of the continence mechanism. Factors associated with SUI in young, nulliparous women include increased body mass index (BMI),^{32,34,35} smoking,^{11,35,42,43} chronic constipation,^{9,32,44} high impact physical activity,^{13-17,34,36-39} oral contraceptive use,^{40,41} sexual activity,¹² and a history of urinary tract infections (UTIs).^{10,32} Familial traits, such as connective tissue composition, have also been suggested as potential factors.^{16,45-48} However, the evidence for most of the lifestyle factors is inconclusive, particularly in young women. There is stronger evidence for familial traits. Currently, the most robust models based on studies of twins suggest that SUI in young women is the result of equal parts genetic predisposition and environmental factors.⁴⁹

2.2.1 Lifestyle Risk Factors

Body mass index has long been considered to be a risk factor in the development of SUI, but the current literature is unclear regarding this association.^{8,11,32,34,35,120-122} In a Swedish questionnaire-based study, the authors found no significant difference between the mean weight of the continent group (64.6 kg \pm 0.5) and the incontinent group (65.8 kg \pm 0.8);¹¹ a finding

supported by another study of Australian university students, which reported that although the women with daily leakage were heavier than those without incontinence, the effect disappeared when adjusted for age.¹² These findings are not supported by the Norwegian EPICONT study (6876 incontinent women and 21,060 controls), which reported that increasing body mass index was strongly associated with SUI, showing a clear dose-response relationship.³⁵ In another Norwegian study, Bø et al. had mixed results relating body mass index to SUI.³⁴ In their study comparing UI in elite athletes and healthy controls, no significant difference was reported in the prevalence of SUI in athletes of differing body mass indices. However, a higher prevalence of SUI was observed in controls with a body mass index of 25 or greater ($p=0.001$). These differing results between the athletes and controls may relate to a lower number of women with high BMI in the elite athlete group or that the damaging stress on the pelvic floors of the elite athletes is similar, regardless of BMI. Alternately, damage from constant loading may not have had time to develop in young women, thus showing no effect of BMI.

Smoking has been suggested as a risk factor for SUI,^{8,11,35,42,43} with two plausible explanations: first, the chronic smokers' cough, as smokers generate greater increases in bladder pressure when coughing than non-smokers,⁴³ and second, smoking has been shown to interfere with collagen synthesis.¹¹ A Swedish-based study of 487 women between the ages of 20 and 59 reported that UI was more prevalent among smokers than non-smokers (OR: 1.78; 95% CI 1.12-2.86).¹¹ An initial analysis of the EPICONT study found that neither former nor current smoking increased the risk for SUI.³⁵ However, when investigations included the number of cigarettes smoked, a dose-response relationship appeared, with a slightly increased and significant odds ratio for greater than 20 cigarettes per day (OR: 1.2; 95% CI 1.0-1.5). The authors also reported a weak dose-response relationship between UI and number of pack years for both former and current smokers. The association between smoking and severe UI was even stronger. However, data on young women with SUI and smoking is lacking. It is possible that no correlation would be found in this population, as there might not be enough time for injuries to the continence mechanism to develop, but further research is required to determine the effects of smoking on SUI in young women.

Chronic constipation is another risk factor for SUI.^{9,32,44} A study from the mid-1980s reported that severely constipated women who had strained at stool for prolonged periods demonstrated damage to the pudendal nerve, potentially affecting urethral sphincter function.¹²³ Another study

investigating bowel function compared 24 women with SUI and 27 controls (mean age: 52 years both groups).⁴⁴ The authors found that significantly more women with SUI strained excessively during bowel movements as young adults (30%), compared to 4% of the controls (p=0.018). Despite the differences in straining as young adults, both groups demonstrated similar rates (9% vs. 8%) of infrequent bowel movements (less than twice a week), suggesting that straining, rather than frequency of bowel movements might be associated with SUI. How constipation affects young women is less clear and further research in this area is required to clarify any correlations.

High impact physical activity has also been linked to increased prevalence of SUI.^{13-17,34,36-39} Indeed, surveys of physically active, young women have found higher prevalence rates for SUI: 41 to 49% in college and elite athletes^{13,34} and 19 to 31% of women in the armed forces,¹⁴⁻¹⁷ compared to prevalence rates of 3.7% to 14% in the overall population of young women.^{4,7-12} One study investigated 291 elite athletes and dancers between the ages of 14 and 51 years, finding that 51.9% of the respondents experienced urine loss during their sport (43.0%) or in daily life situations (42.2%).³⁹ In a comparison between Norwegian elite athletes (n=572) and age-matched controls (n=574) between the ages of 15 and 39 years, the overall prevalence of SUI was not significantly different (41% versus 39%, p-value not reported).³⁴ However, leakage during physical activity was significantly more prevalent among the athletes (29% versus 22%; p=0.009). In both groups, 5% reported SUI to be a moderate to severe problem. In spite of this high prevalence, the aetiology of SUI in this physically active population remains to be elucidated. It has been suggested that high ground reaction forces and increases in intra-abdominal pressure provoked by the activity may unmask SUI.^{13,21,124} It is also possible that the connective tissues and the PFMs can become over-stretched by intense activity over time, resulting in SUI.³⁶ Furthermore, maximum voluntary contraction of the PFMs, as measured by vaginal pressure, has been shown to decrease after 90 minutes of strenuous physical activity, indicating fatigue, possibly increasing the risk of SUI.¹²⁵

The literature pertaining to the association between oral contraceptive use and urinary incontinence is contradictory, with some studies finding positive associations between oral contraceptive use and UI,⁴⁰ some finding negative associations^{10,41} and still others finding no association at all.¹¹ The Nurses' Health Study II of pre-menopausal women, for example, reported that the use of oral contraceptive pills was significantly associated with UI (OR 1.27;

95% CI 1.01-1.59), with the odds of UI increasing significantly with increasing duration of pill use ($p=0.03$ for trend).⁴⁰ Oral contraceptive use was associated with SUI (OR 5.40; 95% CI 1.66-17.50) in nulliparous women despite no significant association in the overall study population (OR 1.04; 95% CI 0.78-1.40). On the other hand, in a study based on the Swedish Twin Registry, oral contraceptive use was found to be inversely correlated with SUI (OR 0.57; 95% CI 0.41-0.79).⁴¹ In order to address the potential covariance of oral contraceptive use and sexual activity, a group of Australian researchers investigating female university students discovered that those who were sexually active and not using a oral contraceptives reported higher rates of UI (21.5%; 95% CI: 16.7-27.3%) than did those who were never sexually active and not using an oral contraceptive (10.1%; 95% CI: 7.0-14.4%) or sexually active and using an oral contraceptive (9.7%; 95% CI: 6.4-14.3%).¹² The group with no reported oral contraceptive use, but who were sexually active exhibited a higher odds ratio of UI than in the group who were never sexually active (OR: 2.17; 95% CI 1.24-3.80; $p=0.007$), suggesting that UI may be related in some capacity to sexual activity. The role of oral contraceptives in SUI and how they may co-vary with other risk factors has yet to be elucidated.

Urinary tract infections are also purported to be associated with UI, particularly in the older population.³² A questionnaire-based study from a community in Sweden investigated this association and found that the number of women who reported urinary tract infections was twice as frequent in the UI cohort, compared to the cohort without UI ($p<0.01$), and occurred most frequently in the youngest group of women (18-30 years);¹⁰ although another study disputed this finding.¹² The mechanisms behind how UTIs affect UI are unclear, particularly in the young population. It is possible that the young women in the Swedish study who were reporting UI were experiencing it while they had a UTI. Alternately, if a young woman has some structural deficiencies (muscle and/or connective tissue), which predispose her to UI, those structural changes may also put her at a higher risk for UTIs. Additional investigations are required to further elucidate these correlations.

2.2.2 Familial Traits

Population-based studies, including twin studies, have permitted the analysis of genetic versus environmental factors related to UI.^{33,49,126,127} Overall, studies have found that 30 to 50% of UI is related to heritability. A large Swedish study of 8452 female twins reported that genetic effects accounted for approximately 41% of the variation in UI, the environmental influence on UI was

of the same magnitude (40%), supporting the idea that the aetiology of SUI is multi-faceted.⁴⁹ An Australian twin and sister study of young, nulligravid women, looked at bladder neck descent on Valsalva, a marker for SUI, and found that approximately 50% of urethral and bladder mobility was related to genetic factors.¹²⁸ A Norwegian study investigated the relative risk of UI amongst mothers and daughters and between sisters.¹²⁷ It found that daughters of mothers with any type of UI were 1.3 times more likely to have incontinence, and that female siblings were 1.6 times more likely to experience UI if their older sisters experienced leakage. An American group compared UI within sister pairs, in which one was parous and the other nulliparous.³³ No significant difference in the prevalence of UI was found between the groups ($p=0.782$), and between the sister pairs the concordance of continence status was 63% ($\chi^2=9.5715$, $p=0.002$), suggesting that familial factors play a greater role than parity in the development of UI.

2.2.2.1 Connective tissue

The extracellular matrix of connective tissue is comprised of collagen and elastin fibres, glycoproteins and proteoglycans, with collagen fibres being the major component.^{129,130} Collagen contributes strength to connective tissue, while elastin gives it elasticity and the ability to recoil.¹³¹ The connective tissue of the pelvic floor plays an important role in the continence mechanism. Without healthy, intact connective tissue, the tensile strength of the fascia and ligaments may be reduced, impairing the relationship between the fascia and muscles, thereby weakening the muscular support system.^{129,132,133}

Collagen. In the early 1990s, researchers discovered that skin fibroblasts produce and secrete 30% less collagen in women with SUI compared to continent women.⁴⁸ When the focus shifted to the continence mechanism, it was found that there was a significant reduction in collagen content in the endopelvic fascia¹²⁹ and in the periurethral musculature in women with SUI compared to those without.^{129,130} Collagen fibres in the paraurethral connective tissue also demonstrated increased diameter and cross-linking, potentially resulting in stiffer tissue, making urethral closure more difficult.⁴⁷ Another study also found that the fibril orientation was less organized and that the fibrils were frequently collapsed or broken.¹³⁰ Keane and colleagues¹³⁴ compared collagen in the periurethral tissue of premenopausal, nulliparous women, with and without SUI. In the women with SUI, collagen content (29% versus 39.7%, $p<0.0001$), type I to type III collagen ratio (65:35 versus 71:29, $p=0.008$), and cross-linking were all significantly reduced. Type I collagen is regarded as the supportive collagen, whereas type III collagen is

found where less rigidity is required. Thus, a decrease in total collagen content, the amount of type I relative to type III collagen and cross-linking would all result in tissue that is less supportive and mechanically weaker.¹³⁴ It is less clear whether there is any change in collagen metabolism, with various studies finding no difference in collagen production,¹³⁵ reduced collagen turnover,¹³⁶ and increased collagenolysis in the periurethral tissue of women with SUI compared to those without.¹³⁷

The discrepancies in the research suggest the possibility that different collagen remodelling pathways may be activated, depending on injury type and severity, mechanical load, genetic and lifestyle factors.⁴⁵ Chen and Yeh⁴⁵ proposed a model to explain SUI development: pelvic tissue in women with a genetic predisposition to SUI exhibits chronic abnormal collagen remodelling, which is modulated by cyclic changes in ovarian hormones, and exacerbated by trauma and mechanical loading of the pelvic floor. They postulated that this abnormal remodelling ultimately disrupts normal tissue architecture and its mechanical properties, resulting in SUI. However, it is also possible that SUI collagen pathways may be implicated in women without a genetic predisposition, as collagen structure is dependent on loading, and loading is altered following injury.^{138,139}

Elastin. While much of the research on the endopelvic fascia has focused on collagen morphology and metabolism, elastin fibres have also been implicated with SUI. Women with SUI have been shown to demonstrate an irregular and fragmented elastin distribution within the periurethral tissue,¹⁴⁰ and an increase in elastase, which is involved elastin degradation.¹³¹ As elastin imparts extensibility and the ability to recoil to a tissue, changes to these fibres may prevent efficient closure of the urethra. Taken together, it is clear that composition and metabolism of both of the major components of endopelvic connective tissue: collagen and elastin, are altered in women with SUI, resulting in stiffer, weaker, less supportive tissues and increased risk of SUI.

2.2.2.2 Muscle changes

Muscular changes in the striated urethral sphincter and PFMs have also been implicated in SUI. A study comparing striated urethral sphincter electromyography (EMG) in 38 women with SUI to 10 continent controls, found that 73% of the symptomatic women demonstrated a lower amplitude, shorter duration EMG pattern consistent with intrinsic muscle damage rather than denervation.¹⁴¹ Those with the altered pattern also demonstrated functional changes, such as

significantly lower Valsalva leak point pressure ($p=0.002$) and more urine loss during pad testing ($p=0.0101$), compared with those with no EMG changes. The authors were not able to comment on the type of muscle damage, but another study found muscle cell apoptosis in the striated urethral sphincter, with concomitant replacement by fat cells and connective tissue, in those over 20 years of age.¹⁴² Intraurethral ultrasound studies have demonstrated decreased thickness of the striated urethral sphincter in women with SUI, potentially supporting the findings of muscular damage in the study above.¹⁴³

Similar findings have been reported for the PFMs. Sixteen women (8 women with and without SUI) underwent MRI evaluation of their PFMs with concomitant surface PFM EMG studies.¹⁰⁸ The results revealed that the pubococcygeus was not as thick in those with SUI ($p=0.04$), and those women also had lower EMG amplitudes ($p=0.03$). PFM thickness correlated with the EMG findings ($r=0.49-0.53$). In a study investigating the relationship between bladder pressure during a cough and PFM surface EMG activity, the investigators found that the EMG activity for a given bladder pressure was lower for those with SUI than for the control group.¹¹² In addition, the effect of continence status was different according to the bladder volume (0, 200 and 400 ml; $p=0.0001$), with the PFM EMG for a given bladder pressure being lower for those with SUI than for the control group, except in the case of the 400 ml filling. This lack of demonstrable difference between the two groups at 400 ml may be because there is increased voluntary PFM contraction as the desire to void increases. In addition, the authors point out that the control group was not healthy, but was rather a group of continent women with overactive bladder syndrome.

2.2.2.3 Functional deficits

Muscle coordination, timing and strength. Prior to a sudden increase in IAP in continent women, urethral pressure rises,^{114,115} and the PFMs contract.¹³³ The increase in urethral pressure occurs 120-200 msec prior to the increase in bladder pressure and is indicative of an intact continence mechanism; this pre-activation is not seen in women with SUI.^{98,115,144-147} Pre-contraction of the PFMs has also been reported in continent women prior to postural perturbations.^{98,116} Compared to continent controls, PFM surface EMG activity in women with SUI was delayed ($p=0.002$) until after a rapid arm movement had begun, rather than acting in an anticipatory fashion.¹¹⁶ During shoulder flexion in the continent women, PFM EMG increased 18.1 (SD 33) ms before the anterior deltoid, whereas PFM EMG increased 5.3 (SD 36) ms after

deltoid initiation in the group with SUI. The pattern was similar with shoulder extension: 26.9 ms (49) prior to posterior deltoid activation for the controls versus 15.4 (43) ms after activation for the women with SUI. Other studies have demonstrated the disruption of this feedforward mechanism in women with SUI when performing leg movements,¹¹⁷ catching a weight,¹¹⁵ and coughing.^{98,118,146}

A study by Thompson et al.¹⁴⁸ investigated abdominal and PFM surface EMG activation patterns in women with and without SUI. With a PFM contraction, the symptomatic group showed lower levels of PFM activation ($p<0.001$) and higher levels of abdominal and chest wall muscle activation ($p<0.01$), when compared to the asymptomatic group. Furthermore, the incontinent women had significantly weaker PFMs on manual muscle testing and appeared to have difficulty isolating the PFMs; rather they globally activated all of the muscles in the region when asked to perform a PFM contraction. The authors proposed that muscle substitution might be the cause of this altered strategy: when a muscle is weakened, there is a shift of motor activity, enabling synergistic muscles to perform the task. Alternately, differences in cortical control, awareness of PFM contraction and muscle coordination in symptomatic women could also be at fault. Another group investigated the influence of abdominal muscle activation on the ability to contract the PFMs in continent women.¹⁴⁹ They found that bladder neck elevation during a PFM contraction (indicating a proper contraction) was influenced by IAP. When the abdominal muscles (obturator internus, obturator externus and rectus abdominis) contracted, the PFMs were not able to overcome the increase in IAP and the bladder neck was not elevated. Combined, these studies suggest that if women are presenting with abnormal muscle activation patterns, or if their abdominal muscles are dominant, then the PFMs may not be able to appropriately respond to an increase in IAP and prevent SUI.

Research findings related to PFM strength in women with SUI differ widely in the literature, varying from decreased, no difference, to increased strength.^{115,121,148,150-152} Chamochumbi et al.¹⁵⁰ investigated PFM strength in 16 continent and 16 women with SUI, with the use of a dynamometer. They found that the anteroposterior active strength for the control group was significantly greater than that of the women with SUI ($0.3\pm 0.2\text{N}$ versus $0.1\pm 0.1\text{N}$, $p<0.01$). However, the lateral strength showed no difference ($0.43\pm 0.1\text{N}$ versus $0.40\pm 0.1\text{N}$, $p=0.2$). In another dynamometric study, a Canadian group also demonstrated that women with SUI have weaker PFMs than their continent counterparts, as measured by absolute endurance, maximal

rate of force development and number of contractions performed ($p < 0.05$).¹⁵¹ Similarly, in a surface PFM EMG study, continent women demonstrated significantly higher PFM EMG amplitudes than the women with SUI ($p < 0.001$).¹²¹ Verelst and Leivseth¹⁵² also compared PFM dynamometric measurements between women with and without SUI, finding no significant differences between the two ($p = 0.153$). Contrary to predictions of the authors, another surface PFM EMG study by Smith et al.¹¹⁵ found EMG amplitudes in women with SUI are greater than in continent women prior to ($p = 0.011$) and during ($p = 0.034$) loading tasks. These findings were also associated with increased EMG activity in the obliquus externus abdominis, which would increase IAP and intravesical pressure, thus increasing the demand on the PFMs and passive structures.^{115,149} The increase in PFM activity may also represent a compensatory mechanism to decrease urinary symptoms.^{98,115}

Madill and colleagues¹²¹ compared maximum surface PFM and abdominal muscle EMG and intravaginal pressure amplitudes among women with mild and severe SUI, and a continent control group. Continent women demonstrated significantly higher PFM EMG amplitudes than both of the groups with SUI ($p < 0.001$), but interestingly, the three groups demonstrated similar vaginal and intra-abdominal pressure measurements ($p = 0.21$ and $p = 0.48$, respectively). The abdominal muscles were also found to be more active prior to the rise in vaginal pressure in the women with SUI compared to their continent counterparts ($p < 0.001$). These findings suggest a multi-faceted causal mechanism in women with SUI. Pelvic floor muscle weakness in women with SUI is supported by the lower PFM EMG amplitudes, and altered fascial support is indicated by the earlier activity in the abdominal muscles relative to the vaginal pressure rise, suggesting the initial force produced by the abdominal muscles was used to take up the slack of pelvis support structures. Altered motor control is implied by the finding that intravaginal pressure was the same in all three groups, even though women with SUI exhibited lower maximum PFM and abdominal EMG amplitudes. Those women likely used different muscle activation patterns to generate this pressure.

When they investigated coughing, Madill et al.¹⁴⁷ found that PFM EMG and vaginal pressure increases were similar between women with and without SUI, suggesting that muscle weakness, at least during reflex contractions, may not be a factor in SUI. They found differences in the timing of muscle activation relative to vaginal pressure, with women with SUI having a slower PFM response. They also found that the women with SUI had higher levels of PFM and

abdominal muscle activation at the point when vaginal pressure began to rise. Again, their findings support the idea that SUI may more likely be due to a combination of altered fascial support and motor control.

Neuromuscular fatigue. As any skeletal muscle can be affected by neuromuscular fatigue, researchers have also investigated fatigue in the PFMs and the striated urethral sphincter.^{113,125,153} Twelve nulliparous women with SUI participated in a cross-over study in which they underwent 90-minutes of interval training and then rested for 90 minutes, or did the activities in the reverse order.¹²⁵ The mean maximal voluntary contraction of the PFMs was decreased by 20% after the strenuous activity ($p<0.01$), suggesting the development of muscle fatigue. These findings are supported by studies using pad testing that have demonstrated greater leakage in the second test.^{75,154} However, in a fatigue task which involved contracting and holding the PFMs for as long as possible, no demonstrable decrease was found in PFM force generation was found in volunteers with and without SUI.¹⁵³

Another group induced fatigue by having volunteers with and without SUI perform seven hard coughs.¹¹³ Maximal urethral closure pressure decreased by 14% in those with SUI, and only 5% in the control group ($p=0.0011$). The same authors investigated the effects of PFM fatigue and increasing cough efforts on the modulation of a pelvic contraction, based on surface EMG from the external anal sphincter.¹⁴⁶ They reported that the strength of the external anal sphincter contraction was modulated to the strength of the cough effort and that performing ten successive strong coughs had no effect on modulation in those with or without SUI. However, ten PFM contractions followed by a maximal PFM contraction sustained until exhaustion significantly decreased the modulation of PFM contraction during increasing cough efforts ($p=0.043$) in those with SUI only. In addition, the timing of the PFM pre-contraction was delayed in the women with incontinence, and the more the pre-activation was delayed, the more the modulation of the pelvic contraction was decreased with increasing cough efforts. The results suggest that the capacity to modulate the PFM response to meet the demands of increased IAP may be affected by fatiguing PFM exercises in women with SUI.

Lumbo-pelvic position. Lumbo-pelvic position has been linked to changes in continence status. In a study by Sapsford et al.,¹⁵⁵ 17 women with and without SUI underwent surface PFM EMG with concomitant surface abdominal EMG. As women moved from slumped to upright sitting, there was a significant increase in resting PFM EMG amplitudes ($p<0.001$). However,

women with SUI had lower PFM EMG in both positions compared to their continent counterparts ($p < 0.05$). Furthermore, women with SUI had significantly less lumbar lordosis than the asymptomatic controls ($p = 0.04$). This last finding is consistent with some previous research into spinal curvature and pelvic organ prolapse.^{120,156,157} In one study, a positive correlation was found between thoracic kyphosis and prolapse; increased kyphosis was associated with higher IAP.¹⁵⁶ Following on the heels of that study, Mattox et al.¹²⁰ chose to investigate lumbar lordosis in relation to pelvic organ prolapse in 363 women. In the women who were diagnosed with an abnormal spine, 91% had a history of pelvic organ prolapse. The most prevalent spinal change was a loss of lumbar lordosis (75%), suggesting that a loss of lumbar curvature may direct more forces onto the pelvic floor and may be a significant factor in the development of pelvic organ prolapse. Nguyen et al.¹⁵⁷ also investigated the relationship between uterovaginal prolapse and the degree of lumbar lordosis and the angle of the pelvic inlet in women with and without prolapse. Women with prolapse had significantly less lumbar curve ($p < 0.003$) and a significantly larger angle of the pelvic inlet ($p < 0.001$) compared to those in the control group. Whether a normal lumbo-pelvic curvature directs the intra-abdominal forces anteriorly to the anterior abdominal wall and pubic symphysis, thereby protecting the pelvic floor,¹⁵⁶ that flattening the lumbar curve brings the pubic symphysis anterior and superior, thereby making the pelvic floor the sole recipient of the downward pressure,¹⁵⁷ or simply that the PFM activity is increased in this position, thereby supporting the pelvic organs,¹⁵⁵ has yet to be determined.

The evidence strongly suggests that SUI has a complicated, multifactorial aetiology. While the evidence from familial studies suggest that 30-50% of SUI is related to heritability,^{33,49,126,127} how the environmental and familial factors interact is much less clear.

2.3 Measurement

Objective assessment of urine leakage is required to determine the severity of a woman's symptoms and to document changes in her symptoms following an intervention. Several testing procedures have been developed to assess various aspects of UI: patient-reported outcome questionnaires (PROs), bladder (urinary) diaries, urodynamic testing, cough stress (paper towel) tests, and pad tests.

2.3.1 Patient-Reported Outcome (PRO) Questionnaires

There are a number of UI specific PRO tools that have been developed to assess a variety of concepts: such as health-related quality of life, symptom severity, symptom bother and patient

satisfaction with treatment. These PROs allow clinicians and researchers to collect standardised data, allowing for quantification and comparison of subjective information. They permit a review of symptom impact and treatment benefit from the individual's perspective, as clinical assessment tends to focus on issues of lesser importance to patients and to underestimate the degree of bother experienced by the patient.⁶⁹ However, it has been reported that a person's perception of continence status and reporting of leakage episodes is modulated by differences in personality characteristics.¹⁵⁸ As such, even though the use of PROs allows the investigator to quantify and compare subjective information, the results do not correlate very well with more objective findings.⁵⁴

Recently, the International Consultation on Incontinence, supported by the World Health Organization, initiated the development of questionnaires for the purpose of assessing different aspects of UI – the International Consultation on Incontinence Modular Questionnaire (ICIQ).¹⁵⁹ All of the modules, which include urinary symptoms and quality of life tools, have undergone rigorous psychometric testing and have published evidence regarding the reliability and responsiveness of the instrument. In addition, the fourth International Consultation on Incontinence has evaluated, rated and recommended multiple UI-specific PROs.⁶⁹ Currently no consensus exists on the most effective scales to use for assessing UI, not because the PROs lack scientific validity, but rather because consensus is lacking on the most important concepts to measure. The Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI) are two commonly used scales to assess health-related quality of life and symptom bother, respectively, in women with UI.⁵³ The IIQ was designed to assess the impact of UI on the activities and emotions of women. The UDI, developed to complement the IIQ, was designed to assess the degree to which UI symptoms are bothersome.¹⁶⁰ Both of these PROs have been validated in women with a diagnosis of UI confirmed with urodynamic testing,^{160,161} but have not been found to be valid in woman without a urodynamic diagnosis of UI, when compared to the one-hour pad test.⁵² Women in the community who have not undergone urodynamic testing may have less severe UI and their symptoms may differ in pathophysiology, compared to those with a urodynamic diagnosis.⁵² In addition, urodynamic studies may have false-negative results, as some studies have found that symptoms are not a good predictor of urodynamic SUI.^{162,163}

Huang et al.⁵⁴ performed a retrospective analysis of 707 women (mean age of 49.8 years) that sought to explore the relationships among quality of life measures (UDI-6 and IIQ-7), symptom

severity (1-hour pad test and the Ingelman-Sundberg severity scale), urethral support (bladder neck angle at rest and with straining, bladder neck rotational angle and funneling) and urethral sphincter function (Valsalva leak point pressure and maximum urethral closure pressure). The scores of both PROs and symptom severity were positively correlated ($r=0.15-0.40$, all $p<0.05$), but the scores on the PROs were not correlated with items related to urethral support or urethral sphincter function. However, item 3 of the UDI-6 (related to SUI) was significantly correlated with bladder neck funneling ($r=0.14$, $p<0.05$) and maximum urethral closure pressure ($r=-0.15$, $p<0.05$). The authors argue that the weak correlations found in the study suggest multifactorial mechanisms behind the pathophysiology of SUI and the complex nature of the subjective perception of SUI. They propose that quality of life and pathophysiological measures play complementary but independent roles in the assessment of SUI.

PROs are valuable tools to assess the subjective experience of the woman with SUI, and they permit the clinician and researcher to quantify and compare that subjective information. However, they do not correlate well with pathophysiological measures and cannot quantify the amount of urine leakage. Including PROs in research and clinical practice is important, but each PRO needs to be selected based on the needs of the investigator, as well as the purpose for which the PRO was developed.

2.3.2 Bladder (Urinary) Diaries

A bladder diary, completed by the patient, is a record of her voiding pattern during her normal daily activities. The information in the diary can include the following: time, amount and type of fluid intake; volume and frequency of urine output; time, provoking activity and severity of UI episodes; degree and provocation of urgency; and pad usage. The goals of the diary are three-fold: 1: to provide the patient with insight into her bladder behaviour; 2: to provide the clinician or researcher with a number of measurements, including UI frequency and approximate quantity of urine loss, and 3: to offer the clinician or researcher insight into the individual's behaviours and habits associated with voiding. In addition, diaries can be used to monitor symptoms and quantify response to treatment.⁵⁶

The diary can be completed over a 24-hour period, or can be as long as seven days. Investigations in older women with SUI have found that it is necessary to complete a seven-day diary to reach internal consistency as determined by Cronbach's alpha measure ($r=0.90$), while only five days are necessary in older women with urge type UI.¹⁶⁴ No similar data exist for

younger women. However, it has been shown that compliance decreases with longer diary duration⁵⁶, with one study reporting a completion rate of 90.7% compared to 50% for three- and seven-day diaries, respectively.¹⁶⁵ A study that evaluated the reproducibility of a seven-day voiding diary in women with SUI found that there was a high correlation between the first three days and the last four days in the number of incontinence episodes ($r=0.887$) and number of daily voids ($r=0.908$), thereby suggesting that a three day chart would be adequate for these parameters.¹⁶⁶

As with other PROs, bladder diaries are self-reported and therefore have the potential to introduce recall bias. Some argue that because subjective history correlates well with a bladder diary in number of UI episodes ($r=0.63$) and pad use ($r=0.81$), a good history-taking might be sufficient.⁵⁵ While filling out the diary, a woman might alter her voiding habits to minimize her trips to the bathroom, decrease her caffeine consumption and/or change her fluid intake to what she perceives to be the “right” amount, skewing the results. However, if completed correctly, including filling out the diary as the events occur, diaries provide real-time documentation of urinary function, reducing recall bias, thereby confirming or disputing clinical history.⁵⁶

A recent literature review found that, while much of the literature on UI describes the use of bladder diaries, there are no studies showing evidence of content validity nor of psychometric testing.⁵⁶ A new urinary diary for the adult population is being developed and tested; this may result in a tool that is psychometrically sound.¹⁶⁷

In summary, bladder diaries are useful to offer the woman with UI and the investigator with numerous, valuable insights into bladder habits. However, some issues related to compliance have been reported, and as it is a self-reported measure, there are concerns regarding recall bias. In addition, some women alter their habits when filling out the diary thereby skewing the results.

2.3.3. Urodynamic Testing

Urodynamic testing is an invasive functional study of the lower urinary tract, requiring the insertion of catheters into the urethra, bladder and rectum.^{50,57} Urodynamic testing includes a battery of different tests for diagnosing various lower urinary tract disorders, including SUI. “Urodynamic” or “genuine SUI” is diagnosed when involuntary urine leakage is observed with an increase in intra-abdominal pressure during the filling phase of the study, in the absence of detrusor contraction.⁵⁷ Two other tests are also used in the diagnosis of SUI. The urethral pressure profile is assessed by continuously recording pressure while gradually withdrawing a

fluid-infused catheter from the urethra; it represents an idealized concept of the ability of the urethra to prevent leakage.^{50,57} Abdominal leak point pressure is a measure of the urethra's ability to act as a valve to contain the urine within the bladder during coughing or Valsalva,⁵⁰ it is determined by recording the abdominal pressure at the moment when urine loss is observed from the external urethral meatus.⁶³

Urodynamic testing has been considered for many years to be the cornerstone of lower urinary tract dysfunction assessment. However, new studies are calling this position into question.^{62,64-66,168,169} A recent systematic review by Weber⁶⁴ concluded that some commonly evaluated urodynamic parameters, such as static urethral pressure profilometry or cough profile parameters are not standardised or reproducible and, therefore, are not able to contribute to the differential diagnosis in women with SUI symptoms. Poor reproducibility is due to large variations within and between patients, because of both biological variation and variation within testing procedures.^{57,64} In addition, Weber⁶⁴ reported that maximum urethral closure pressure values in women with and without SUI overlapped so greatly it was impossible to select a cut-off that differentiates continence from incontinence. As well, this wide overlap would also make it impossible to determine minimally important changes.

Many believe a low leak point pressure is diagnostic of intrinsic sphincter deficiency, thus defining the mechanism of SUI and predicting that surgical treatment will more likely fail.^{62,63} However, leak point pressure measurements have not yet been standardised for testing position (supine, semi-recumbent, sitting, standing or standing with foot on stool), nor for the Valsalva or cough effort.¹⁶⁸ Furthermore, it has been suggested that leak point pressure is more likely to measure to symptom severity than to define the underlying mechanism of SUI.⁶² However, a more recent study found no correlation between leak point pressure and incontinence severity as measured by either the Sandvik Incontinence Severity Index, the number of pads used, or the number of incontinence episodes.¹⁶⁸ In addition, no correlation was found between leak point pressure and quality of life measures (UDI-6, IIQ-7, Prolapse and Incontinence Sexual Function Questionnaire short form-12, and Short Form-12, a generic measure of health-related quality of life). Taken together, these findings seriously question the utility of the leak point pressure as either a diagnostic test, or as a measure of symptom severity.

In summary, urodynamic testing for SUI is not standardised or reproducible, and is not accurate enough to detect minimally important changes. In addition, the diagnostic equipment for

these studies is expensive and requires specialized personnel. Furthermore, while urine loss can be visualized with urodynamic testing, that leakage cannot be quantified.

2.3.4 Cough Stress (Paper Towel) Tests

A cough stress test is a simple test to diagnose SUI: the woman coughs forcefully with a full bladder, while the investigator or clinician watches for urine leakage from the urethra. It can be performed in supine or standing.⁵⁸⁻⁶⁰ The stress test uses a yes/no scoring system, in that urine loss is either observed or not. This method of scoring does not allow for quantification of urine loss, offering no way to differentiate between minor and severe incontinence, nor for detecting minimally important changes.

Holding a paper towel to the perineum while the participant coughs and then calculating the size of the wet area on the towel (paper towel test) is a modification of the original test that allows the urine loss to be quantified.⁵⁹ In a study investigating within- and across-visit test-retest differences, the paper towel test was repeatable within visits (visit 1: $p=0.18$ and visit 2: $p=0.59$) and between visits ($p=0.87$). The paper towel test has been recommended for small amounts of urine loss (0-6 ml) because of the absorbency of the towel; for volumes greater than 6 ml, it has been suggested that a pad should be used instead.

The advantages of both of these tests are the immediate availability of the results and their simplicity, but the validity of the tests may be limited by the participant's effort and bladder volume. Varying the testing position affects the results, as coughing provokes more urine leakage in standing compared to sitting or supine,¹⁷⁰ likely due to significantly increased bladder pressures in standing,¹⁷¹ and the improved effectiveness of the cough in upright positions, due to the more advantageous position of the diaphragm.¹⁷² However, it has been noted that it is challenging for the practitioner to observe urine loss in standing;⁶³ as well, testing in standing can be more time-consuming and difficult to perform.¹⁷³ With the use of the paper towel test though, the difficulties in observing the urine loss are overcome.

An investigation into the association between self-reported SUI (questionnaire) and the paper towel test was insignificant ($r=0.12$ to 0.27).⁶⁷ The questionnaire overestimated the volume of urine lost in 83% of the cases. This finding suggests that either the paper towel test was insufficiently provocative to elicit the volume of urine loss that the individuals typically experience, and/or that individuals' subjective assessment of "some" or "a lot" of urine leakage was smaller than the researchers'. The results of this study are consistent with an older study that

found the cough stress test was only positive in 64% of women with SUI, reflecting a notable number of false-negative findings.¹⁷⁴

In a study comparing the cough stress test to a 24-hour pad test in 55 women, the stress test was found to be more in agreement with urodynamic results (89% of women, kappa correlation coefficient =0.51) as compared to the pad test (60% of women, kappa correlation coefficient =0.08).⁶⁸ Using the urodynamic results as a reference, the cough stress test had 90% sensitivity and 80% specificity, while the pad test had 60% sensitivity and 60% specificity. However, one would expect to see strong correlations, as the cough stress test used some of the same procedures as the urodynamic testing, including retrograde bladder filling. The investigators noted that 42% of the participants preferred the pad test compared to 29% favouring the cough stress test, primarily because the pad test was more comfortable and less embarrassing to perform. Furthermore, as previously discussed, there are inherent challenges in using urodynamic testing as a reference, given that the tests have not been shown to be reliable or specific.

Cough stress tests assess for urine loss associated with SUI, which can be quantified with the modified paper towel test. The modified paper towel test is repeatable up to 6 ml of urine loss. However, some women find these tests embarrassing to perform.

2.3.5 Pad Testing

The objective of pad testing is to quantify the volume of urine lost by weighing an absorbent pad before and after some type of leakage provocation.⁶⁹ Pad weighing was first described in 1971 by James et al.,¹⁷⁵ but it was not until 1981 that a standard set of activities was applied to the testing.¹⁷⁶ It is inexpensive, non-invasive and easy to administer, and both the World Health Organization and the International Continence Society (ICS) recommend using pad testing as a method to detect and quantify urine loss.⁵¹ There are two kinds of pad tests: home-based (e.g. 12, 24 and 48-hour tests) and office-based (e.g. short, one-hour and two-hour tests),⁵¹ with the type of test chosen depending on the goals.

Home-based tests were developed to measure urine loss during a person's typical daily activities. These tests are not intended to be provocative, but rather to determine the typical severity of leakage experienced by a woman on a daily basis. As such, these longer tests are not very structured, do not differentiate between stress and other types of UI, and they are difficult to reproduce. While the validity of a home-based test has been confirmed,¹⁷⁷ clinical reports

indicate that patients who expect to experience considerable incontinence may compensate for this by voiding more frequently and/or drinking less, thus weakening the validity of the pad test.^{76,174} A pad weight gain of greater than 4.4 grams is considered positive for a 24-hour test, allowing for weight increases from perspiration and vaginal discharge.¹⁷⁸

Office-based tests (up to 2 hours in duration) were developed to overcome the difficulties of the longer tests. They involve the performance of a structured set of activities developed to elicit leakage. Some of these tests include manoeuvres to induce urge UI, and others are strictly exercise-based, to elicit SUI only. The benefits of the short pad test include: they are quick and easy to perform, they provide immediate results, and compliance of the participant can be directly monitored.^{80,178-180} A pad weight gain of greater than 1.4 grams is considered positive for a 1-hour test.¹⁷⁸

Home-based pad tests may be more representative of a woman's daily urine leakage, as the participant undergoes her activities of daily living, but the tests are not able to differentiate between urge UI and SUI. In addition, some have voiced concerns over fluid loss secondary to evaporation prior to weighing the pad,^{179,181} and others have reported decreased compliance in returning the pad for weighing.^{74,180} On the other hand, office-based pad tests use a standard bladder volume and activity protocol, and they permit the investigator to structure the test so that it only provokes SUI. Since the exercises are standardised and are designed to provoke urine leakage, the shorter tests are more reproducible.⁷⁰

Since the first pad test protocol was published in 1981,¹⁷⁶ there has been much debate in the literature as to whether pad testing has merit and if so, what the protocol should include. It became apparent quite rapidly, for example, that bladder volume should be standardised, as urine leakage was observed to increase with urine load.⁷² Many investigators suggested filling the bladder to a certain percentage of cystometric capacity (e.g. 50, 75 or 100%) or standardised amount (e.g. 250, 300 or 500 ml),^{71,73-75,77,151,154,182,183} while others argued for fluid loading with a standardised amount (500 or 1000 ml) and type of drink (sodium-free or orange juice).^{78-80,174,184} A study comparing three different short pad tests with varying bladder volumes (unknown bladder volume, 250ml of infused saline, and after drinking 500ml water with a one-hour wait), found that none of the tests were significantly correlated with each other. However, the test in which the participants drank water an hour prior had the fewest false negatives (6%) compared to saline infusion (9%) and unknown capacity (21%).¹⁸⁵

For the tests that involved fluid loading, the timing of the exercise portion of the protocol after drinking became a topic of discussion. In order to ascertain when to start a pad test after fluid loading, Haylen et al.¹⁸⁶ assessed baseline bladder filling rate in 20 parous women (mean age 48.9 years; range: 31-77). The women were then catheterised and asked to drink one litre of fluid (usually fruit juice) as quickly as possible. The mean time (SD) to achieve diuresis of greater than 5 ml/min. was 42.8 (18.4) minutes. The mean time (SD) to return to baseline filling rate was 124.5 (19.8) minutes. Based on these findings, the authors determined that pad application and exercising should take place between 60 and 120 minutes after the fluid load, as women are nearing their bladder capacity and, thus, are more likely to leak urine. Other investigators concluded that urine load (starting volume and diuresis) needed to be included in the analysis for the most accurate results.^{72,184}

Another study investigated whether a fixed bladder volume increased the accuracy of pad testing.⁷⁵ Thirty-three women (mean age 56 years; range: 38-83) with SUI had their bladders infused to 75% of urodynamic capacity, and then performed a 12- to 15-minute pad test. The volunteers then voided, their bladders were artificially refilled to 75% of capacity, and the test was repeated. The correlation between the amount of urine lost in the first and second tests was good ($r=0.74$, $p<0.001$), and the leakage was consistently greater in the second set of tests, a finding supported by others.⁷⁴ No correlation was found between the amount of urine lost and the severity of UI, as judged by symptoms (Ingelmann-Sundberg severity score). The authors suggested that this lack of association was likely because the physical exertion required of the participants during the test exceeded that of their daily activities and that intolerance of small amounts of leakage varies widely and is highly subjective, making grading difficult.

Based on the studies from the 1980s investigating various aspects of a short pad test protocol, the ICS established guidelines in 1988 for pad testing to ensure standardisation, practicality and repeatability (See Table 2.1 for the details of all of the pad tests discussed.).¹ The guidelines include test length (1 hour), amount and type of fluid drunk (500 ml of sodium-free liquid), activities performed, and type of statistical analysis to be used (nonparametric, as the results are not normally distributed). However, by the early 1990s, Hahn and Fall⁷³ developed their own pad test, with four goals: that it be provocative enough to demonstrate mild SUI, be quick, so as to minimize variations due to diuresis, correlate well with the woman's history, and be easy to perform. Fifty women with SUI who were referred for surgery (mean age 52 years; range 30-79;

parity not reported) performed the pad test with a fixed bladder volume, which was repeated one to seven days later. The two separate tests were highly correlated ($r=0.94$, $p<0.001$) and the pad test was highly sensitive, with no false-negatives. The authors suggested that testing should all be done by one investigator to standardise investigations as closely as possible, and that all tests should be done at the same time of day and same phase of menstrual cycle, to minimize sources of error.

Around the same time, Petros and Ulmsten⁷⁸ also developed a pad test that was more aggressive than the ICS test. Forty-six women referred to a gynaecology practice (mean age 43 years; range 24-67; mean parity 3; range 1-7) started with 300 ml in the bladder and performed a series of exercises over the next 3-4 minutes. Intravesical pressure was also measured during the different activities and the results indicated an approximate linear relationship between intravesical pressure and urine loss. The authors justified the development of a new pad test by arguing that the ICS test does not precisely define what it is trying to measure: SUI or urge UI, which is “the complaint of involuntary leakage accompanied by or immediately preceded by urgency.”¹ Differentiation between the two types of UI is clinically very important, as the aetiology, and thus treatment, of each problem varies considerably. In addition, the authors argued that the majority of the ICS test activities generate low bladder pressures (e.g. stepping, bending, coughing), versus the high pressures of jumping on a trampoline, thus representing only those women with severe SUI. Of the 38 women with SUI symptoms, 34 had a positive pad test and the authors suggested that even the trampoline test could not generate sufficient pressure to provoke SUI in all patients who reported leakage with a sneeze.

Most recently, Rimstad et al.¹⁵⁴ also increased the load of their pad test. One hundred and forty-seven women with SUI presenting to the obstetrics and gynaecology department for incontinence investigations underwent progressively more challenging tests, starting with a cough stress test in supine, then jumping jacks, and finally jumping jacks on a small trampoline. The trampoline test was able to document SUI in all except one woman (99%), while the jumping test captured 136 (93%), and the supine test 72 women (49%). Repeatability of the trampoline test was tested a few minutes after the first in 19 women ($r=0.80$, p -value not reported), with greater leakage during the second test ($p=0.04$).

Table 2.1: Pad Test Protocols

Authors	Test length	Drink or retrograde filling	Volume in bladder	Activities
ICS (Abrams et al, 1988)¹	1 hour	Drinks 500 ml sodium-free liquid	Unknown	Walk, including stair-climbing one flight up and down (30 min.); Stand up from sitting (10 X); Cough vigorously (10 X); Run on the spot (1 min.); Bend to pick up object from floor (5 X); Wash hands in running water (1 min.)
Hahn et al., 1991⁷³	5 min.	Retrograde filling	50% of bladder capacity	Climb up and down 100 steps; Cough vigorously (10 X); Run on spot (1 min.); Wash hands in running water (1 min.); Jump feet together (30 sec.); Jumping jacks (30 sec.)
Petros et al., 1992⁷⁸	3-4 min.	Retrograde filling	300 ml	Cough (10 X); Pick up pen up from the floor (10 X); Wash hands in running water (30 sec.); Step up and down a step (20 X); Star/scissor jumps (10 X); Jump on a mini-trampoline (10 X)
Persson et al., 2001⁷⁷	1 min.	Retrograde filling	300 ml	Jumping jacks (20 X); Run on the spot with high knees (20 X); Jump up and down (20 X)
Morin et al., 2004¹⁵¹	20 min.	Drink 1 litre water (control group) Retrograde filling (SUI)	> 250 ml (confirmed by ultrasound) 250 ml	Walk, including stair-climbing one flight up and down (10 min.); Stand up from sitting (10 X); Cough vigorously (10 X); Run on the spot (1 min.); Bend to pick up object from floor (5 X); Jumping jacks (10 X); Wash hands in running water(1 min.)
Rimstad et al., 2013¹⁵⁴	3-4 min.	Retrograde filling	300 ml	Cough vigorously in supine and standing (3 X) each; Jumping jacks (20 X); Cough vigorously standing on trampoline (3 X); Jumping jacks on trampoline (20 X)

Several authors have attempted to shorten the one-hour pad test, for the benefit of the woman, the investigator, and to decrease the impact on health care spending.^{77,78,154,182} Persson et al.⁷⁷ recruited 47 parous women who had presented to the obstetrics and gynaecology office for urinary incontinence concerns (median age 49 years; range 29-64) to perform a short pad test with retrograde bladder filling to 300 ml. The test was repeated 5-10 minutes later with good reproducibility (median urine loss 8.5 ml; range 0±60 ml; p=0.26). The bulk of the evidence suggests that shortening the pad test does not decrease its reproducibility, therefore making these tests good options for assessing urine loss.

Most of the above studies were performed in specialists' offices and used retrograde filling during their pad test. While retrograde filling can increase the accuracy of the pad test,⁷⁴ the procedure requires specialized equipment and technicians, which are both expensive and potentially difficult to access. Furthermore, this type of bladder filling compared to the natural filling following fluid consumption, may be less acceptable to women and poses the potential risk of introducing a urinary tract infection.

A more recent study by Morin et al.¹⁵¹ used a dual-stream approach to bladder filling: the women with SUI had their bladders artificially filled to 250 ml, while the women without SUI drank one litre of water one hour prior to testing, with bladder volume (at least 250 ml) confirmed with ultrasound. Eighty-nine parous women presenting to an obstetrics and gynecology clinic (range 21-44 years) participated in the study using a modified 20-minute pad test to quantify and verify the symptoms of SUI. Fifty-nine women reported symptoms and 30 were symptom-free. The pad test demonstrated high sensitivity and specificity, with all symptomatic women and none of the asymptomatic women leaking during the pad test.

Several researchers have compared the one-hour pad test to other methods for objectively assessing urine leakage.^{68,77,184} Jorgensen et al.¹⁸⁴ compared it to a standing cough stress test, and voiding cystourethrography: a technique for observing SUI on fluoroscopy. The pad test was found to be the most accurate for correctly diagnosing SUI (34/49 participants), followed by the stress test (17/49) and finally, by the voiding cystourethrography (16/49). The latter two tests produced false negatives approximately 50% of the time. Persson et al.⁷⁷ also compared their pad test to the standing cough stress test and it was, again, found to be more sensitive (92% versus 74%; p=0.05). Others have compared the results obtained from one-hour pad tests with 24 and 48-hour pad tests. For the most part, weak or no correlation has been found between the two

types of pad test.^{174,187} These findings are not surprising as the longer pad tests measure the leakage provoked by an individual's typical daily activities, whereas the shorter test is more likely to reflect the competence of the urethral sphincter by challenging the full bladder to withstand increased IAP.¹⁷⁷

A South Korean study investigated whether incontinence severity as measured by a one-hour pad test correlated with urethral mobility, leak point pressure and maximum urethral closure pressure in 274 women.⁷⁶ Leak point pressure was the only urethral parameter correlated with the severity of SUI, with a weak inverse correlation to pad test weight ($r=-0.383$, $p<0.005$). In addition, the low leak point pressure group had greater urine loss on pad testing than the higher leak point pressure group ($p<0.05$), thereby significantly predicting the objective severity of SUI. Based on their findings, the authors suggested that the pad test should be considered one of the most important tests for the evaluation of women with UI. The relationship between subjective severity of UI and pad tests has also been investigated. Frazer et al.¹⁵⁸ compared the severity of UI assessed with a self-reported visual analogue scale and a 2-hour pad test and found no correlation between the two. They reported that most subjects stated that the pad test was true reflection of their UI and argued that the lack of correlation related to subjective variability in the participants' perception of the severity of their UI, not to weaknesses in the pad test.

Despite the establishment of the ICS guidelines for pad testing in 1988,¹ a systematic review from 2002 found that, out of the 75 papers evaluated, only 25 reported using the guidelines.¹⁸⁰ In fact, how the pad tests were conducted and reported varied so much in the studies reviewed that it was difficult to compare them and to interpret the differences. For tests performed in the clinic, for example, there were differences in the starting bladder volume or the amount drunk, the activity schedule and the length of the test. Although not presented in the systematic review, some past explanations for altering the ICS protocol include: shortening the testing time, improving accuracy, limiting the test to SUI only, and increasing ease of performance.^{70,73,78,80,154} The recommendations of the systematic review included that the ICS guidelines should be reviewed and revised, and that further development and validation are needed to produce pad tests which are clinically significant, realistic, practical to perform and relevant to women with SUI. Another systematic review supports these recommendations,⁵³ but to date, no such revision has been published.

In summary, home-based pad tests assess the incontinence experienced during activities of daily living, and they are not meant to be provocative. These longer tests are unable to differentiate between stress and urge UI, and are difficult to standardise. Short pad tests provide one way for clinicians to assess the symptoms of urinary incontinence. The tests are non-invasive, easy to perform, provide immediate results, and allow the clinician to limit the activities associated with SUI only. However, no such test has been developed for young, healthy women with SUI.

2.5 Conclusion

Effective treatment for SUI requires that clinicians understand the severity of the problem and the underlying deficits. Office-based pad testing is the only one of the aforementioned measurement procedures that can quantify small and large amounts of urine loss. Having an adequate measure for SUI severity such as the pad test, will assist clinicians to improve their ability to diagnose SUI causes. In a study that presented case studies to specialists in the United Kingdom, the authors concluded that pad test outcomes did influence treatment planning.¹⁸⁹ For both clinical application and future research, identifying a pad test sensitive to treatment interventions will help to improve patient care.

Based on the literature review, no pad test protocol exists for young, nulliparous women with SUI. SUI in young, nulliparous women is a serious problem and an appropriate tool for assessing symptom severity is lacking. The current literature of incontinence assessment tools has been studied in older parous women, approximately 50 years of age. In addition, most of the protocols include hand washing, an activity used to elicit urge UI, which is an exclusion criterion in the present study. This SUI-specific pad test was created to be more aggressive than previously published tests, to challenge the young pelvic floor. It was hypothesized that this novel pad test would demonstrate good reliability⁸³ and specificity in young, healthy women between the ages of 18 and 30 years.

CHAPTER 3 METHODOLOGY

Ethics approval for the study was received from the University of Saskatchewan Biomedical Research Ethics Board (BioREB 12-179). Volunteers were recruited via advertisements posted across the university campus and on the online student portal. Potential volunteers contacted the researcher by email or telephone and they were screened for inclusion by telephone. The screening questionnaire (Appendix B) included the 3 Incontinence Questions (3IQ);¹⁸⁹ and questions about oral contraceptive use and history of pregnancy. Inclusion criteria were female, between the ages of 18 and 30, and able complete twenty minutes of vigorous physical activity. Those who reported symptoms of SUI were in the experimental (incontinent) group and those who had no UI were part of the control (continent) group. Women who reported symptoms of urge incontinence were excluded from the study. Each volunteer was provided with the Research Participant Information Sheet (Appendix C) for review prior to the first appointment.

Methods, definitions and units conform to the standards recommended by the International Urogynecological Association and the International Continence Society joint report on the terminology for female pelvic floor dysfunction⁵⁷ and the standards of documentation in pad test reporting.¹⁸⁰

Preliminary pad testing was based on the pad test protocols of Bø¹⁸² and Morin et al.⁸¹ (Appendix A).

3.1 Pad Test Protocol

Participants were instructed to wear appropriate exercise clothing (e.g. t-shirt, shorts and running shoes) to the testing sessions. One hour prior to testing, each participant was asked to drink one litre of water and not to empty her bladder until after the testing procedure was complete. Upon arrival for testing, the Research Participant Information Sheet (Appendix C) was reviewed, any questions were answered, and the consent form was signed. Next, the woman's height and weight were measured. She was then given a pre-weighed (Mini Digital Scale, Chestnut Tools, Almonte, ON) brown paper bag containing one incontinence pad and a plastic, resealable bag. The scale was accurate to one gram and to improve the reliability of bag weights, each bag was weighed three times. If there was discrepancy between the weights, the mode was recorded. The volunteer was asked to place the pad in her underwear in the privacy of a bathroom, keeping all the pad wrappings in the paper bag. The pad test was then performed.

Following the pad test, the participant was permitted to void and instructed to place the pad in the plastic bag, putting it, along with the wrappings, into the paper bag. The paper bag was then re-weighed. To test repeatability, the pad test was performed on two consecutive days, at approximately the same time each day (within 2 hours) to minimize confounding influences, such as fatigue and differences in fluid consumption (e.g. coffee, tea).

Each woman was instructed to perform the activities in the pad test protocol with maximal effort. She was encouraged to not prevent any leakage from happening, either by slowing or stopping the activity, or by contracting her pelvic floor muscles. If the participant needed rest in between activities, she was given as much time as required.

For a warm-up, the volunteer walked up and down 40 steps at her own pace, after which the pad test was performed. The pad test started with the participant running up and down 40 steps twice (80 steps), taking approximately one minute; and then completing 1 minute intervals each of the following activities:

- standing up from sitting;
- sit-ups/curl-ups with feet on plinth;
- running on the spot,
- jumping jacks;
- jumping on a 100 cm diameter exercise trampoline (Tempo Fitness);
- 10 vigorous coughs.

The participants were offered standardised encouragement at 30 and 50 seconds for each of the timed tests.

3.2 Statistical Analyses

Data were analyzed statistically using Minitab 16 and SPSS Statistics 21 software. A ranked repeated measures ANOVA was used to evaluate differences between the continent and incontinent groups and the testing sessions. The model included continence status and the testing session as fixed factors and the participant as a random factor. The interaction between continence status and testing session was included in the model. Intraclass correlation coefficients (ICCs), two-way mixed effects model, were computed for each group to estimate how closely the data from each participant matched from day one to day two.

CHAPTER 4
RESULTS

Sixteen nulliparous women aged 22 to 29 years (mean: 26.06±2.08) participated in the study. Participant demographics are presented in Table 4.1. The mean body mass index (BMI) for the sample was 21.88 kg/m² (±1.92, range 19.4-25.5). Seven of the volunteers were continent (controls) and nine had SUI. Seven women (3 with SUI; 4 controls) were using hormonal contraceptives. There were no dropouts and all the participants completed the testing without incident.

Table 4.1: Participant demographics

	Age (years) (mean±SD)	Weight (kg) (mean±SD)	Height (m) (mean±SD)	BMI (kg/m²) (mean±SD)
Continent (n=7)	25.71 ± 2.27	64.93 ± 5.11	1.75 ± 0.08	21.20 ± 1.78
SUI (n=9)	26.33 ± 1.94	61.27 ± 8.08	1.65 ± 0.05	22.36 ± 1.86
Total (n=16)	26.06 ± 2.08	62.87 ± 6.99	1.70 ± 0.08	21.88 ± 1.92

The mean increase in pad weight for both testing sessions was 0.64 g (±0.50) in the continent group and 11.89 g (±20.32) in the group with SUI. The repeated measures ANOVA found that the interaction between testing session and continence status was not significant (p=0.721), nor was there a change in pad weight between the testing sessions (p=0.228). Pad weights between the two groups of women were significantly different (p=0.023).

Intraclass correlation coefficients (ICCs) were computed for each group, using a two-way mixed effects model, to estimate how closely the data from each participant matched from day one to day two. The ICC for the continent group was 0.845 (95% CI: 0.139–0.973) and 0.782 (95% CI: -0.040–0.952) for the group with SUI.

The test was unable to elicit measurable urine loss in three participants with SUI, resulting in three false negatives.

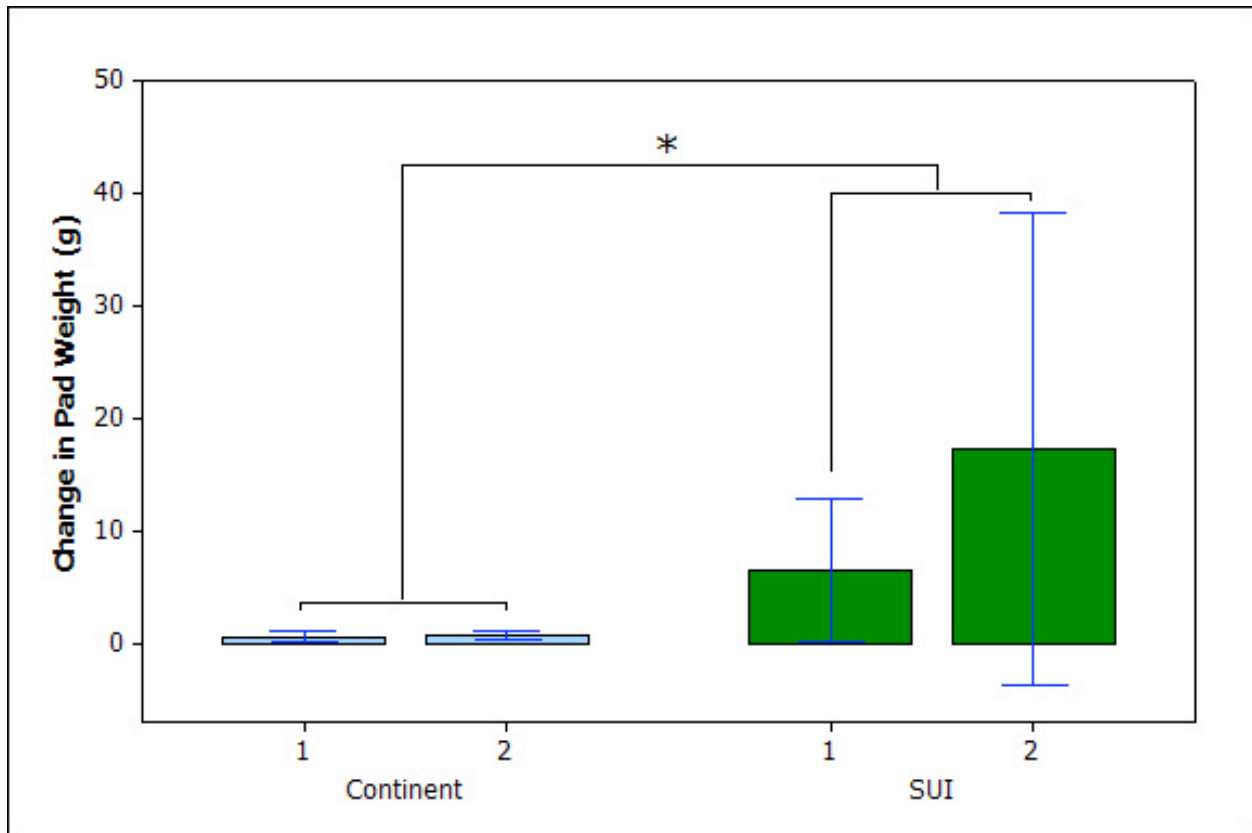


Figure 4.1: Pad weight and continence status.

Differences in pad weight by testing session and continence status. Bars indicate mean change in pad weight and whiskers indicate the 95% CI of the mean. 1= first testing session; 2 = second testing session; * indicates a significant difference ($p=0.023$).

CHAPTER 5 DISCUSSION

The purpose of this pilot study was to determine the reliability and accuracy of a new, standardised pad test designed specifically to assess urine leakage in young, healthy women with SUI. The findings from this study indicate that this novel pad test is reliable and can differentiate between young, nulliparous women with and without SUI. This new pad test has excellent potential for clinical use in younger women, as it is more provocative than previous pad tests.

5.1 Methodology

One of the strengths of this study was that it was designed to address a population that is under-represented in the SUI literature. The majority of the women who have participated in past research relating to SUI have presented to a clinic, often a surgeon's office, seeking treatment for their SUI. In addition, most of those women were older than 30 years and were parous. The women who volunteered for this study were nulliparous, under the age of 30, and represent a younger female population with SUI symptoms, not being followed or identified within the health care system. Indeed, women who are symptomatic with SUI but have not presented to their health care provider represent the majority, 80.2% according to one study.²⁰ These differences in study populations may also represent variation in the pathophysiology of the SUI symptoms and also, potentially, severity.

This study was conducted using a novel pad test because preliminary testing (Appendix A) found that previously published pad tests were not challenging enough to elicit urine leakage in young, nulliparous women.¹⁵¹ The preliminary study did not provoke any significant difference in urine leakage between the women with and without incontinence in this population. This novel pad test incorporated several important modifications from other protocols in order to develop a more sensitive tool that was specific to SUI, and to address population-specific concerns, not previously addressed in the literature. Hand washing, which is used to elicit urge incontinence, was removed from the protocol to make this test more specific to SUI. The fluid load was increased to one litre from the 500 ml recommended in the ICS guidelines based on the findings of the Haylen et al.¹⁸⁶ study from 1988, which concluded that pad application and exercising should take place between 60 and 120 minutes after the one litre fluid load, as women are nearing their cystometric capacity, and are more likely to leak urine. Unlike Morin et al.,¹⁵¹ we did not have the tools readily available to scan the bladder, but based on previous literature

and participants' spontaneous comments, their bladders should have been full. Finally, the activity schedule was changed by increasing the duration of the tasks and by adding jumping on a trampoline, as the original activities were deemed not to be provocative enough to elicit SUI in these young women. Both Petros and Ulmsten⁷⁸ and Rimstad et al.¹⁵⁴ added mini-trampolines to their activity protocols, suggesting that the pressures generated while jumping on the trampoline might be closer to those generated by sneezing.⁷⁸

5.2 Between Group Testing

Pad weight was found to be significantly different between groups. The pad weight gain in the group with SUI was less than pad weight changes reported in other studies.^{70,185} The range of mean urine loss reported in the literature varies from 17 to 54 g,^{70,72-74,81,154,184,185} with the highest losses reported for a population of women referred for SUI surgery.⁷³ When comparing the volunteers from this study to other study populations, ours is younger and did not present at a clinic for assessment of SUI symptoms, potentially accounting for the smaller amount of mean urine loss.

All of the asymptomatic women had a pad weight gain of less than 1 g, so there were no false positives. This small change in pad weight suggests that, under indoor, climate-controlled conditions, the test did not stimulate significant vaginal secretions or perspiration. Furthermore, it suggests that any pad weight gain of greater than 1 g can be interpreted as quantifiable incontinence. These findings fit with the recommendations in a review of pad testing, which proposed that the upper limit for pad weight gain in an asymptomatic woman, should be between 1.0 and 1.4 g.¹⁷⁹

Leakage was not quantifiable in three women who reported symptoms of SUI. This does not indicate that the participants did not leak at all, rather that their leakage was less than 1 g. This amount of SUI might still be bothersome, but would not be enough to be quantified with this test. Alternately, as was proposed by Petros and Ulmsten,⁷⁸ it is possible that the forces generated during the testing procedures were not sufficient to replicate those forces produced during very provocative actions of daily life, such a sneeze, or high impact physical activities. In addition, some women may only experience SUI when their PFMs are fatigued, and it is possible that the pad test did not tire the PFMs sufficiently to compromise the continence mechanism in three volunteers. Phases of the menstrual cycle have also been associated with changes in SUI symptoms, and may represent another potential reason for negligible urine loss.^{190,191}

Three of 46 women in the Petros and Ulmsten⁷⁸ study did not lose urine in their pad test, and to address this problem, the authors had the participants repeat the trampoline jumping to further challenge the continence mechanism. While this additional test promoted SUI in all participants, the pad test then lacked standardisation. In another study by Persson et al.,⁷⁷ 3 of 34 women did not leak during the pad test. The population of women in both of these studies was older, parous and had presented to a clinic for assessment of SUI symptoms. These characteristics suggest that the pathophysiology of the SUI was different and potentially more severe, thereby having a lower percentage of false negatives compared to the current study.

5.3 Day-to-Day Repeatability

The novel pad test presented here provoked similar amounts of urine loss on the two consecutive testing days, demonstrated by the high ICCs for each group, which are similar to correlation coefficients found in studies using other pad tests.^{70-73,75,184} One needs to interpret the ICCs with caution however, as the confidence intervals are wide, which is consistent with other studies.^{71,192} This is likely due, in part, to the small sample size of this pilot study, but also with the variability in the amount of leakage between women.

There was a trend (5/9 women) towards greater leakage on day two in the symptomatic group, which is consistent with several other studies.^{74,75,154,192} Some of the reasons for this trend may include: neuromuscular fatigue, increased effort, physiological relaxation, and/or psychological relaxation.^{75,77,192} The clinical implication of increased leakage on a second test is that the test may always need to be done twice to get an accurate measure of leakage.

5.4 Implications for Practice

It has been well-established that SUI in young nulliparous women is a serious problem and that an appropriate tool for assessing and quantifying leakage is lacking. This study could have far-reaching clinical implications as this new pad test could be utilized and integrated into the management practices of UI specialists, including physical therapists, gynecologists, nurses, and other health care providers. Given that existing one-hour pad test results influence change of management practices (e.g. surgical versus non-surgical intervention),¹⁸⁸ a more accurate test for young nulliparous women could have substantial benefit in directing treatment. This novel pad test could be used to determine the minimally clinically important changes occurring with various interventions for women with SUI. As research shows there is a higher incidence of SUI in elite athletes, our pad test could also be used to investigate SUI in young athletes. It also might

prove valuable in assessing the temporal fluctuations in urine leakage in young, healthy women, such as during different stages of the menstrual cycle.

5.5 Limitations

There are a few limitations of the study that should be noted and considered for future research. First, as this was a pilot study, the sample size was small. Small samples affect the variation of the data to have greater impact on statistical power; however despite the small sample size, a significant difference was found. A larger sample may be more representative of the population studied. Second, three false negatives were revealed, possibly suggesting that the test was not challenging enough to stress the continence mechanism, or that it provoked less than 1 g of urine loss. Last, during this project we did not assess bladder volume prior to the pad test. While all the women expressed that their bladders felt very full, this was not quantified. Differences in starting urine volume between testing sessions could negatively affect the test-retest repeatability.

5.6 Conclusions and Recommendations

5.6.1 Conclusions

The purpose of this pilot study was to determine the reliability and accuracy of a new pad test to evaluate SUI in young, healthy women. It can be difficult to provoke urinary leakage in healthy young women, despite self-reports of SUI. This challenge is likely because they have experienced little damage to their pelvic floors, such as through parity, ageing and elevated BMIs, and that their leakage is usually triggered by relatively high intra-abdominal pressure. The results of this study support the use of this pad test in healthy young women with SUI; it appears to be challenging enough to cause measureable urine loss in the majority, including those with low BMI, and it may be useful for diagnosing and quantifying SUI without urodynamic studies.

5.6.2 Further research suggestions:

Based on this study, a number of recommendations can be made for further research:

- i. Increasing the study sample size would provide more accurate estimates of the typical amount of urine leakage experienced by a broader representation of SUI severity,
- ii. Investigating how many repetitions of the pad test are required until the leakage stabilizes,

- iii. Methods to assess small, but bothersome amounts of leakage should be tested in this population. For example, participants might take riboflavin supplements with their fluid load to colour their urine,⁷⁸ or oral phenazopyridine to differentiate urine from other body fluids.¹⁹³
- iv. Methods to improve the assessment of the starting bladder volume, such as transabdominal ultrasound, could be added to further standardise the test protocol, thereby improving day-to-day repeatability.

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APPENDIX A
PRELIMINARY TESTING DATA

Table A.1 Descriptive Statistics for Preliminary Pad Test

	Age (years) (mean)	Weight (kg) (mean)	Height (m) (mean)	BMI (kg/m²) (mean)	Pad weight (g) (median, range)
Continent (n=7)	25.43	63.90	1.70	22.16	0, 0-1
SUI (n=6)	27.00	71.73	1.68	25.45	1, 0-2
Total (n=13)	26.15	67.52	1.69	23.68	1, 0-2

APPENDIX B
SCREENING QUESTIONNAIRE

Instructions: *This questionnaire can be administered by the research co-ordinator in person or over the phone.*

Thank you for considering taking part in our study assessing a new pad test for young, healthy women with urinary leakage. The following questions help us to determine if you are eligible for this study and include questions about urinary leakage, your level of physical activity and use of medications. It will take approximately 2 minutes to complete. You are not obligated to answer any questions that you are not comfortable with.

Date of birth: _____

Please answer the following questions to the best of your knowledge:

1. During the last 3 months, have you leaked urine (even a small amount)?

Yes No

2. During the last 3 months, did you leak urine:

(check all that apply)

a) When you were performing some physical activity, such as coughing, sneezing, lifting or exercise?

b) When you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough?

c) Without physical activity and without a sense of urgency?

3. During the last 3 months, did you leak *most often*:

(check only one)

a) When you were performing some physical activity, such as coughing, sneezing, lifting or exercise?

b) When you had the urge or the feeling that you needed to empty your bladder, but you could not get to the toilet fast enough?

c) Without physical activity and without a sense of urgency?

d) About equally as often with physical activity as with a sense of urgency?

4. Is there any reason that you might not be able to complete 20 minutes of physical activity, including running up and down stairs, jumping jacks, sit-ups and coughing?

Yes No

If yes, please explain: _____

5. Are you taking any hormonal contraceptives such as: oral contraceptives (“the pill”), injection (Depo-Provera), patch (Ortho-Evra) or IUD (Mirena)?

Yes No

6. Have you been pregnant for longer than 20 weeks?

Yes No

7. What is your preferred method of communication for booking appointments?

Phone

Email

8. Would you be willing to be contacted for future studies related to pelvic floor and incontinence research?

Yes No

9. Next appointment for reviewing consent form: _____

Thank you for your time.
If you have any questions, please call Juliet at the School of Physical Therapy
(University of Saskatchewan)
Email: juliet.sarjeant@usask.ca
Tel: 306-966-8619

APPENDIX C
RESEARCH PARTICIPANT INFORMATION SHEET



UNIVERSITY OF SASKATCHEWAN

Research Participant Information Sheet

Development of a pad test to assess stress urinary incontinence in young, healthy women: a pilot project

Scientific Investigator:

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Study Location: School of Physical Therapy

Introduction:

You are invited to take part in a research study in the School of Physical Therapy at the University of Saskatchewan because you responded to the request for participants and have undergone the telephone screening process. Please read the following information sheet and ask as many questions as necessary before you decide whether to participate. Please take the time to read the information carefully and to discuss it with your family, friends or doctor before you decide whether or not to take part.

Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, it will not affect your academic standing, employment or medical care, as applicable.

Funding to cover the costs of conducting this study has been provided by the University of Saskatchewan. The researchers are not receiving any financial gain from conducting this study.

Why is this study being done?

Stress urinary incontinence (SUI) is the involuntary leakage of urine with coughing, laughing, sneezing or vigorous physical activity. Anywhere between 7 and 16% of women between the ages of 18 and 30 experience SUI. In female college athletes, the incidence of SUI rises to 49%.

Pad tests are simple tests that use a self-adhesive pad in a woman's underwear to measure urine leakage over a set amount of time or with a set amount of activity. A pad test is not invasive, it is easy to administer, cost effective, and can diagnose incontinence and determine its severity. However, most pad tests are used to assess SUI in older women who had had babies. Such tests are not likely to be vigorous enough to elicit leakage in healthy, young women who have not had babies.

The purpose of this study is to develop a new tool to measure urine leakage in young, healthy women with SUI. We will be collecting information from twelve (12) volunteers. Should this tool be effective in testing SUI in young women, we will use it in another study investigating the effects of the menstrual cycle on urinary leakage. Together, the results of these studies may lead to changes in the way researchers and health care professionals test young women with SUI, which may lead to improvements in treatment for these women.

Who can participate in the study?

Women who are eligible for this research must:

- be between the ages of 18 and 30
- be able to complete twenty (20) minutes of vigorous physical activity: running on the spot, standing up from sitting, running up and down stairs, sit-ups, jumping jacks, jumping on a small trampoline and vigorous coughing.

What does the study involve?

This study will involve collecting data on two (2) consecutive days for approximately twenty (20) minutes each.

First testing session: All testing will be performed by the research co-ordinator, a female physiotherapist with ten (10) years of clinical experience. The test procedure will be thoroughly explained before starting the test.

You will be asked to come to the School of Physical Therapy for twenty (20) minutes of testing. Testing may be done individually or in a group setting. You will be asked to drink one (1) litre of water one (1) hour prior to the test start time. It is important that you do not empty your bladder between the time you drink the water and the end of the testing session. We encourage you to wear or bring appropriate running shoes and a t-shirt and shorts.

The pad test involves performing twenty (20) minutes of physical activity (running on the spot, standing up from sitting, running up and down stairs, sit-ups, jumping jacks, jumping on a small trampoline and vigorous coughing) while wearing a self-adhesive pad that you will place in your underwear, like a menstrual pad. This pad will be weighed before and after the test to determine the amount of urine loss.

Second testing session: The pad test will be repeated the following day at a mutually convenient time.

What are my responsibilities?

As a study participant, you will be expected to:

- a. Follow the directions of the research co-ordinator; and
- b. Report any changes in your health to the research co-ordinator.

What are the possible risks and discomfort?

There is a small risk of physical injury from activities such as running up and down stairs, jumping on a small trampoline, performing jumping jacks and sit-ups. In order to address this, the environment for the pad test will be set up to minimize any risks and you will be given an opportunity to warm up prior to the vigorous activities. Wearing appropriate running shoes, shorts and a t-shirt will also decrease any chance of injury.

What are the benefits of participating in this study?

There are no guaranteed benefits for you from participating in this study. We believe that the information gained from this study will improve our knowledge about SUI so that assessment and treatment strategies can be enhanced to benefit other women with SUI.

What if new information becomes available?

If, during the course of the study, new information becomes available that may be related to your health or your willingness to participate, this information will be provided to you by the research co-ordinator.

What will the study cost me?

You will not be charged for any research-related procedures. You will not be paid for participating in this study. Reimbursement for study-related expenses (e.g. travel, parking, meals) is not available.

Will my participation in this study be kept confidential?

In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the research team. It is the intention of the research team to publish results of this study in scientific journals and to present findings at related conferences, workshops and in the Master's thesis of the research co-ordinator, but your identity will not be revealed.

What happens if something goes wrong?

In the event of a research-related injury, you will need to seek immediate medical attention at no additional cost to you. You are not waiving your legal rights by agreeing to participate in this study.

What happens after completion of the study?

If desired, we will provide you with some information about SUI and a list of physiotherapists in Saskatoon specially trained to assess and treat women with SUI.

Should you be interested, the results of the study will be provided to you, when they become available.

What happens if I decide to withdraw?

Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. If you choose not to participate in, or you withdraw from, the study, your future academic status and medical care will not be affected. If you wish to withdraw from the study, please notify the study personnel as soon as possible and the appropriate arrangements will be made.

The study may be stopped or you may be removed from the study at any time. Reasons for this may include injury, failure to follow study instructions, administrative reasons or if the study investigators decide that it is in your best interest to withdraw you from the study.

If you voluntarily withdraw from the study, or if you are withdrawn, and you do not want your data to be used in the study, please contact the study personnel and your data will not be used for research purposes.

Questions/Contact Information:

This study has been reviewed and approved on ethical grounds by the University of Saskatchewan Research Ethics Board (BIOREB 12-179 and date). The Biomedical Research Ethics Board is responsible for the protection of human participants involved in research studies. All study-related procedures will be performed in compliance with Good Clinical Practice guidelines set forth by Health Canada for the conduct of research with human participants.

If you have any questions regarding your participation in this study, please feel free to contact Juliet Sarjeant (MSc Candidate, Research Co-ordinator) at 306-966-8619 or Dr. Stéphanie Madill (Principal Investigator) at 306-966-6570.

If you have questions about your rights as a research volunteer or concerns about the study, please contact the Chair of the Biomedical Research Ethics Board, c/o Ethics Office, University of Saskatchewan at 306-966-4053. Collect calls will be accepted.

Research Participant Consent Form

Development of a pad test to assess stress urinary incontinence in young, healthy women: a pilot project

I have read the attached Research Participant Information Sheet, and I freely and voluntarily agree to take part in this study.

I understand the purposes and procedures and the possible risks and benefits of the study.

I was given sufficient time and opportunity to ask questions and to reflect on my understanding of, and participation in, the study. My questions have been answered to my satisfaction.

I agree to fully cooperate with the study personnel and will tell them of any injuries that I sustain during the study.

I am free to withdraw from the study at any time, for any reason, and I am aware that this will not affect my future medical treatment.

I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.

I understand that by signing this document I do not waive any of my legal rights.

I will be given a signed and dated copy of this consent form.

I would like to receive a copy of the study results:

yes no

Participant Signature: _____

Participant Name (please print): _____

Date: _____ Time: _____

Investigator/Delegate Signature: _____

Investigator/Delegate Name (please print): _____

Date: _____ Time: _____