Validation of the English-Language Pelvic Floor Inventories Leiden (PelFIs) Administered Questionnaire

by

Kelli Berzuk

A Thesis submitted to the Faculty of Graduate Studies of

The University of Manitoba

in partial fulfillment of the requirement of the degree

MASTER OF SCIENCE (REHABILITATION)

Department of Medical Rehabilitation

University of Manitoba

Winnipeg

ABSTRACT

Purpose

To accurately and precisely evaluate the validity and reliability of the English-language Pelvic Floor Inventories (PelFIs) administered questionnaire.

Participants

Fifty female patient volunteers (ages 24 to 82 years) plus fifty female control volunteers (ages 21 to 83 years) completed the 149-item questionnaire.

Methods

The English-language PelFIs was read to the patients and control participants by qualified pelvic floor physiotherapists, as this is an administered questionnaire. Participant responses were then recorded by the therapist with the exception of participants marking the line on a visual analogue scale for necessary items.

Analysis

Items of each of the 9 domains (Micturition Pattern, Urinary Incontinence, Obstructive Micturition, Pelvic Organ Prolapse, Defecation Pattern, Fecal Incontinence, Constipation, Pelvic Floor Pain and Sexual Dysfunction) relating to pelvic floor dysfunction were analyzed using SPSS software. Construct validity between the domains of the patient population and the control population was assessed using Discriminant Analysis. Findings of between-group differences where $p<0.05$ were considered significant. Independent t-tests comparing each patient domain to its corresponding control domain was also used to determine construct validity, with $p<0.05$ used for significance. Content validity was attained by seeking advice from a variety of experts in the field appropriate to the domains and the document as a whole. Test-retest reliability was addressed by asking patient volunteers to complete the English-language PelFIs on two separate occasions (with a two-week separation period) with differing pelvic floor physiotherapists administering the tool. This subsample data was analyzed by looking at the association between time-one to time-two (between each domain as well as the document as a whole) using Intraclass Correlation Coefficient (ICC) with the acceptable coefficient for group differences being ICC=0.70. Internal consistency was determined by correlating items within domains. Pearson's Correlation was used to detect differences between domains, with the acceptable coefficient for group differences being 0.70. Cronbach's alpha was determined for each domain with 0.70 as the critical value.

Results

Construct validity of the English-language PelFIs was established by quantifying the differences in prevalence of pfm dysfunction between the patient population and the control population. Very significant findings of $F=10.83$, $p<0.0001$ were found for the document as a whole. T-tests for the domain comparisons showed significance for all 9 domains ($p<0.0001$ for all domains with the exception of domain Defecation Pattern which found significance at $p=0.0048$). Content validity was attained by experts, and additional information gathered for further improvement of this tool. Test-retest reliability for all domains was established with $ICC=0.905$, $p<0.0001$. No significant differences were found between time-one and time-two. Internal consistency was obtained with significant Pearson's Correlation of $r=0.72324$ ($p<0.0001$) for domains Obstructive Micturition and Urinary Incontinence, $r=0.73703$ ($p<0.0001$) for domains Pelvic Floor Pain and Constipation, and $r=0.87025$ ($p<0.0001$) for domains Sexual Dysfunction and Pelvic Floor Pain. Four additional domain combinations approached significant findings. Cronbach's alpha was found greater than 0.70 for all domains with the exception of domain Sexual Dysfunction. The prevalence of co-occurrence of pfm disorders with patients presenting for treatment of a single pfm dysfunction was quantified and 100% of the patients reported symptoms in other domains, additional to the domain they sought treatment for. The presence of pfm dysfunction was also quantified in the control population and 94% were found to display symptoms of pelvic floor dysfunction.

Conclusions

This administered questionnaire was shown to be valid and reliable in the English language. Information was gathered, from experts, for direction to segments of the document that may benefit from enhancement to further strengthen the PelFIs as well as identification was made of the highest information-eliciting questions for future expansion to a short-version assessment device. Development of the English-language PelFIs is important for medical practitioners working in the field of pelvic floor dysfunction, not only as a diagnostic and assessment tool, but also as an outcome measurement for treatment and research.

ACKNOWLEDGEMENTS

This thesis would not have become reality without the help and guidance of my advisor, committee, colleagues, friends and family. I would like to take this opportunity to express my gratitude for their kindness and support. Also, it has been an honour to join my Dutch colleagues in this international research study and I wish them continued success with their project.

Thank you to Dr. Barbara Shay for the endless hours of mentorship as my advisor. It has been an honour and pleasure to learn from you. The knowledge you patiently passed on to me will be fondly remembered and put to good use. I look forward to continuing to learn under your gracious tutelage. To my committee members, Dr. Jessica Cameron, Dr. Ken Maslow and Dr. Shay, thank you for your suggestions, feedback and re-direction as well as making the time in your demanding schedules to advise me through this process. Your guidance was invaluable for my initiation into the exciting world of research and your kindness in doing so made every step a positive experience.

Thank you to Dr. Anne Katz, Dr. Maggie Morris, Dr. Rob Bard, Dr. Ted Lyons, Dr. Ken Maslow, Dr. Richard Silverman, Dr. Michael Stephensen and Dr. Nobby Woo for taking the time to complete the content validity evaluation of the PelFIs. I have enjoyed working with you and your patients for many years and was moved when each of you immediately agreed to assist me with this project. Your willingness to help me meant more than you know. Thank you also to Dr. Tom Hassard, for your endless guidance and for showing me the fun side of statistics.

To my colleagues, coworkers, patients and friends at IPPC—Incontinence & Pelvic Pain Clinic, thank you so much for all of your help in making this project possible as well as fun. To my Mom and Mother-in-law, it is a special feeling when family and career blend together and turn a work task into a poignant life memory. Thank you to my whole family; my source of never-ending support and motivation in everything I do. Thank you always.

I dedicate this Masters Thesis

to my loving husband Cal

and our beautiful little angels, James and Cassidy.

Your constant love and support is my motivation, always.

Thank you.

Table of Contents

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION

The clinical focus of pelvic floor physiotherapists is to positively impact the lives of patients suffering with pelvic floor dysfunction on both subjective and objective levels. Subjectively, physiotherapists aim for improvement in the quality of life of their patients and objectively they seek reduction or resolution in frequency and intensity of the symptoms that led them to seek medical attention.

For this to occur, both quantitative and qualitative measuring tools, proving to be valid and reliable, need to be accessible. Furthermore, uniformity in evaluation of pelvic floor dysfunction allows for better comparison and learning for pelvic floor physiotherapy on a global perspective.

Pelvic Floor Inventories Leiden (PelFIs)

The Pelvic Floor Inventories Leiden (PelFIs) is a promising research tool that has been shown as both valid and reliable in the Dutch-language and required English validation so that it could become accessible to clinicians on a worldwide scale (1).

The PelFIs is an administered questionnaire and is unique in its fully encompassing focus to all aspects of pelvic floor muscle (pfm) function (complaints of pelvic organ prolapse, micturition, defecation, pelvic floor pain and/or sexual function due to pfm dysfunction) and offers complete thoroughness as well as history-taking uniformity. As such, the English-language PelFIs stands to make a significant

contribution to pelvic floor physiotherapy, translating into higher quality care for patients experiencing pfm dysfunction.

Relevance

While the prevalence of pfm dysfunction is very high, affecting many millions of women worldwide in differing ways (social, occupational, physical, sexual, psychological, domestic, relationship, financial, etc.), most people have no, or limited, knowledge or awareness of this muscle and therefore do not have, or seek the tools to prevent or correct these disorders (1, 2).

The pfm holds the great responsibility of ensuring proper bladder or bowel control as well as contributing to sexual function, supporting the pelvic organs so that they are able to properly function, assisting in respiration and, finally, the pfm offers core stabilization/postural support and assists in biomechanics for everything from simply maintaining a static posture, to lifting and ambulating. When the pfm is neglected, bowel and bladder incontinence, constipation, obstructive micturition, pelvic and sexual pain, pelvic organ prolapse and/or low back pain may result. Pfm dysfunction comes in many variations and affects millions of people in numerous ways. Research is in demand for all areas of pfm dysfunction and standardized and validated tools are necessary for the building of this research.

REVIEW OF THE LITERATURE

Bladder Dysfunction

According to the Mayo Clinic website, June 2002, one out of every two female Americans will suffer from urinary incontinence at some point in their lives (3). North of the border we find the same concerns with Canadian women and bladder dysfunction. An international study of 4500 women in 9 countries, presented by the International Continence Society (ICS) in Florence, Italy 2003, found that Canada had the highest incidence of stress urinary incontinence (SUI) in the countries studied (2).

The ICS study unveiled an overall lack of awareness regarding SUI and recommended that a campaign directed at the female public, focusing on female urinary incontinence education and awareness, was warranted. Only 2% of those women suffering with SUI knew the name of their disorder. This study stated that the impact of SUI included negative effects on career, physical activity, intimacy and sex, self-confidence and self-esteem, social activity, freedom and vitality (2).

A Canadian study in 2004 looked at the pfm of women suffering with SUI and compared them to women not experiencing SUI symptoms. The researchers used dynamometric measurements to objectify characteristics of the pfm such as passive force to determine resting tone level, hold-time of contraction to determine absolute endurance, number of rapid contractions in a 15-second interval, and maximum strength of pfm contraction. This study showed impairment in the pfm of the incontinent women in both a decrease in resting tone as well as a decrease in ability to sustain pfm contraction. This study further noted that the absolute maximum strength between the

two groups was not significantly different. This finding explained why we occasionally see women experiencing SUI who are able to generate decent muscle contraction for a minimal amount of time, erroneously leaving women feeling that their pfm is strong and healthy. Sufficient maximum strength, while an important pfm characteristic, is only one of the many factors of muscle assessment necessary for overall good health and function (4). For example, if the pfm cannot sustain this contraction and quickly fatigues, incontinence may result, as the urethral closing pressure is not maintained. Additionally, if pfm resting tone is abnormally high, the pfm may not fully relax on the urethral sphincter during voiding leading to incomplete bladder emptying or pain with voiding. Hypertonicity can also lead to difficulty with bowel function and painful intercourse (5). Low pfm resting tone leads to SUI by not effectively closing the urethra. If the pfm does not exhibit a healthy resting tone, the tone may fluctuate between high and low resting levels.

Problems with bladder urgency and frequency can be distressing for those suffering, with or without incontinence. The American Nobel Study (6) found that previous estimates of 17 million Americans and 50 to 100 million people worldwide suffer from overactive bladder symptoms, may actually be understated. Further, people affected by overactive bladder symptoms often feel that their lives are being controlled by their bladders, thus leaving them resistant to leave their homes. This can have a devastating effect on these individuals mentally and physically, as their worlds become smaller in social contacts as well as geographically, since they prefer to stay near their homes and washroom facilities (6).

Bowel Dysfunction

Bowel dysfunction can be embarrassing, frustrating and often devastating. A study looking at the bowel function of women who have given birth, found that 36% experience occasional fecal incontinence and 74% of these parous females experienced incontinence of gas (7).

Stewart et al., (1990) conducted telephone interviews of over 10,000 Americans over the age of 18, to determine bowel habits for the past 3-month period. This research found that 14.7% of the subjects experienced constipation (8). Iantorno et al., (2006) looked at patient-referrals over a 10-year span for evaluation of constipation. Of these patients, those determined to be experiencing functional constipation, were further evaluated for colonic transit time, pelvic floor function and anorectal function. Functional constipation refers to a healthy bowel that is not functioning properly, often due to diet and lifestyle. This can lead to difficulty with bowel emptying due to colonic inertia, delayed transit or pelvic floor dysfunction. Pelvic floor dysfunction (determined by abnormal straining during anorectal manometry, abnormal balloon expulsion, and defecography testing) was noted in 76.3% of patients with functional constipation making pelvic floor dysfunction the most common cause. Slow transit constipation (greater than 72 hours) was noted in 8.4% of patient. Constipation-irritable bowel syndrome (according to Rome I criteria of functional constipation for greater or equal to 3 months, straining at defecation at least 25% of the time, lumpy and/or hard stool at least 25% of the time, sensation of incomplete evacuation at least 25% of the time, or 2 or less bowel movements per week) was found in 10.7% of the patients. The remaining

4.6% of the functionally constipated subjects had no other symptoms fulfilling the three categories (9).

Pelvic Organ Prolapse (POP)

Lack of support from below to pelvic organs can lead to the bladder, uterus or bowel sitting in a less than optimum position. While women rely primarily on the connective tissue from above for organ suspension, support from below helps to decrease the downward pull of gravity over time and the extra weight during pregnancy that may stretch this superior support structure. By assisting from below, undue strain in the downward direction is alleviated.

Once organs begin to protrude caudally, discomfort and even pain may be noted, and most women find organs protruding through the vagina distressful and embarrassing. Many women note the 'lump' protruding vaginally or rectally when wiping following voiding or defecation. For some it is bothersome for aesthetic reasons, while others are troubled by physical discomfort or even pain.

Furthermore, it is easy to envision that, when the pelvic organs are not supported in their intended position, there may be dramatic impact to the function of the prolapsing organ. Bladder and bowel emptying may be compromised when these organs are falling in a caudal direction, often compressing their outlets. Functionally, this can lead to incomplete emptying of the bladder and/or bowel. If the bladder is not properly emptied, there is an increased risk of infection, as well as bothersome symptoms such as bladder urgency, frequency and incontinence. When the bowel angle is altered, incomplete bowel emptying can occur leading to constipation and fecal incontinence. As

well, if the uterus is prolapsing, pelvic pain and sexual dysfunction may result from pressure of the sagging uterus and physical impact of the uterus during intercourse. Sexual and pelvic pain may also result from bladder or bowel prolapse as these organs tend to fall in posterior and anterior directions respectively, in addition to their downward fall with gravity. This may cause encroachment in the vaginal canal and again be bothersome due to downward pressure as well as the physical impact during intercourse.

In 1999, gynecologist Dr. Bob L. Shull, estimated that 43 million American women over the age of 65 would experience some degree of POP by 2030, almost double from the 23 million women with POP at the time of his prediction (10). Recent statistics appear to support his forecast. In 2004, a Netherlands study showed that 40% of women ages 45-85 experienced significant pelvic organ prolapse. The researchers in this study noted that poor coordination of pfm contraction was likely to be causative in POP (11). POP is not only physically and emotionally upsetting, it also has dramatic financial impact. It is believed that in the USA over $1 billion is expended for the more than 200,000 annual surgeries related to POP and approximately 30% of these are repeated procedures (12).

Pelvic Pain

The International Pelvic Pain Society (IPPS) found that chronic pelvic pain affects 9.2 million American women ages 18-50 and 61% of these women do not have a diagnosis. IPPS claims that chronic pelvic pain has reached epidemic proportions and remains very poorly understood (13).

IPPS defines chronic pelvic pain as any pain in the pelvic region for greater than six-months' duration. They state that underlying tissue damage often produces acute pelvic pain. Following six months of pain, IPPS notes that the progression of the chronic pain itself becomes the disease. It is described as the unrelenting pain leading to changes in behavior and emotion producing a complex that becomes the diagnosis known as "chronic pelvic pain syndrome" (13).

IPPS explains that while chronic pelvic pain may begin in one organ, over time other organs may become dysfunctional as well. This is because prolonged pain may lead to chronic tensing of the pfm and subsequent injury to this muscle. As this muscle is directly related to the other pelvic floor organs in both proximity and function, these neighboring organs may too become dysfunctional. For this reason, what may begin with uterine pain, perhaps with a diagnosis of endometriosis, may eventually lead to bowel dysfunction and/or bladder dysfunction with corresponding pain in these organs (13). Often the organs affected secondarily produce pain that overshadows the initial pain. This may explain why some women with endometriosis continue to experience chronic pelvic pain even following hysterectomy.

Referral of pain via myofascial pain syndromes may also explain pain in sites other than the origin (5, 13). Travell and Simons (14) describe the concept of myofascial pain and how ailing muscles may refer pain to other bodily areas. For the pfm they supply us with details suggesting that perineal pain as well as pain in the urogenital structures may arise from myofascial trigger points found in the ischiocavernosus and bulbospongiosus muscles of the pelvic floor. They explain that aching perineal pain and dyspareunia (specifically, painful entry during sexual intercourse) can occur from

trigger points in the bulbospongiosus muscle. For men, trigger points in this muscle may be a contributor to symptoms of erectile dysfunction. Further to this, they explain that trigger points noted in coccygeus and levator ani muscles may produce sacrococcygeal and vaginal pain and that trigger points in the sphincter ani muscle of the pelvic floor may produce anal pain and disrupt bowel function and proper emptying. Conversely, defecation may aggravate the levator ani muscle pain. Additionally, vaginal pain and anococcygeal pain may result from myofascial trigger points located in the obturator internus muscle (14).

Sexual Dysfunction

Sexual dysfunction may be seen in patients with pelvic pain or independent of symptoms of pain. The National Health & Social Life Survey studied 1749 women and found that 43% experienced sexual dysfunction (15). Painful intercourse is just one of the many sources of sexual dysfunction. Other common sources of sexual dysfunction are inhibition or anxiety related to sexual activity, decreased or lack of pleasure with sexual activity, difficulty or inability to achieve orgasm, and lack of lubrication with sexual activity. Research findings show 11.3% of women experience pain with intercourse (16).

Gordon et al., (1999) examined several bladder dysfunctions related to different etiologies to see if they differed in the effects on sexual function. They showed that overall sexual function scores in women with detrusor instability were significantly lower when compared with scores of women suffering with stress urinary incontinence or mixed incontinence. This study grouped the females according to age with women

over 60 years old labeled as “elderly women” and those 60 and under being the “younger group”. While previous to the completion of the questionnaire only a single woman in the study acknowledged having urinary incontinence during sexual activity, the questionnaire revealed that 3% of the “elderly women” and 29% of the “younger women” had in fact experienced this. None of the women in the study sought medical attention for this symptom. The results of this study confirmed the presence of sexual dysfunction in all ages of women suffering with urinary symptoms, especially detrusor instability (also known as overactive or irritable bladder and refers to the sudden need to void) and, therefore, the researchers encourage medical assessment of sexual function in all women reporting symptoms of bladder dysfunction (17).

Studies have shown that while sexual dysfunction can be associated with pelvic floor dysfunctions such as pelvic organ prolapse and incontinence (18, 19), improving strength and health of the pfm can improve sexual function, desire and performance including orgasm (20).

Dean et al., (2008) looked at women 3-months post-partum and again at 6-years post-partum, and compared sexual function to birth delivery mode, use of pelvic floor strengthening exercises and symptoms of urinary and fecal incontinence. This study was based on questionnaire evaluation with 7879 women responding at 3-months and 4214 at 6-year post-partum. While no statistical significance was noted between delivery mode and sexual function, there was a significant relationship found for sexual function and the remaining two variables. Not all of the participants chose to complete the optional sexual function component of the questionnaire. Of those that did, 17.5% selected the most-negative option as their response to at least one of the sexual function

questions indicating significant dysfunction (21). Women who had exclusively cesarean sections had more positive perceptions of sexual satisfaction for both their partner and themselves compared to women who had vaginal and instrumental deliveries. No other domains in sexual function were significantly different between the two groups (21).

For the women performing pelvic floor exercises compared to those not participating in pfm exercise, statistical significance was noted in 7 of 10 sexual function domains with exercising women scoring higher in all domains of sexual desire, sexual arousal and orgasm. It should be noted that exercising women with incontinence were separated for analysis and this subgroup did not show significantly better scores for sexual arousal to those not performing pfm exercises. Also, of the women incontinent of urine who were also completing their exercises, sexual pain was higher than the non-exercising group. The researchers speculate that this may be due to the presence of a stronger pfm (secondary to exercise) combined with the apprehension of possible leakage leading to pfm hypertonicity and spasm causing sexual pain. This is supported by the fact that this domain also showed less sexual pain for the continent women performing pfm exercises compared to those not exercising their pfm (21). Finally, for the incontinence variable, both urinary and fecal incontinence showed significant adverse effect on sexual function. In fact, for bladder and bowel incontinence, adverse effect on sexual function was noted in every possible domain such as pain with intercourse, poor sexual satisfaction, difficulty with orgasm, lubrication and sexual arousal (21).

PFM Dysfunction Overall

While the impact of any form of pfm dysfunction can be distressing, research has demonstrated that a delay and even avoidance of seeking medical treatment is common practice. The ICS study presented earlier found that 62% of women with SUI had never consulted a physician and, of those that did, 20% waited up to three years, and 10% waited for four years or more before talking to their doctor about their symptoms. This study also showed that 33% of women experiencing SUI believed nothing could be done about their disorder (2). It has been shown that in addition to patients being reluctant to discuss symptoms of bladder incontinence, medical practitioners share this resistance. This supports the statement by the World Health Organization referring to urinary incontinence as one of the "last medical taboos" (22).

Millions of Canadians suffer with varying forms of pfm dysfunction often leading to significant negative impact on quality of life. Urinary incontinence, for example, can lead to emotional disturbances and social isolation (2, 23, 24). Despite the disturbing influence both physically and emotionally, resistance to seeking medical attention remains an obstacle. A study by Pharmacia Canada found that approximately 2.9 million Canadians suffer from overactive bladder symptoms yet less than 20% seek treatment. They showed that enjoyment and frequency of sexual relationships are negatively affected by more than 50% of those afflicted with overactive bladder symptoms and close to 20% have chosen to not participate in romantic relationships because of their bladder dysfunction. Overactive bladder symptoms negatively impact hugging and cuddling and many of the participants withdraw from intimacy altogether and yet 80% will not speak to their doctors to receive help (24).

While women resist discussing symptoms of pelvic floor dysfunction, it is important to note that many women with one pelvic floor dysfunction will also be afflicted with other dysfunctions, often unknowingly, in the remaining pelvic organs. It is therefore critical that medical care practitioners ask questions regarding all types of pelvic floor dysfunction and not only those relevant to the organ being presented with symptoms.

In a 2008 study looking at the prevalence of pelvic floor disorders in a sample of 1961 American women, 23.7% of these women had one or more pelvic floor dysfunctions; POP in 2.9%, urinary incontinence for 15.7% and fecal incontinence in 9.0% of the women polled. However, this study did not look at the other forms of pelvic floor dysfunction such as pelvic and sexual pain and therefore, the reported finding of 23.7% of women with pelvic floor dysfunction may actually underreport the prevalence of all pelvic floor dysfunction in American females (25). Further to this, another 2008 study published in the Obstetrics & Gynecology journal found 37% of their 4130 female study sample had at least one type of pelvic floor dysfunction (SUI 15%, overactive bladder 13%, POP 6%, anal incontinence 25%). Again, this 37% does not include those suffering with pelvic pain and sexual dysfunction (26). Interestingly, this study also noted high co-occurrence in pelvic floor disorders. Of those suffering with bladder dysfunctions of SUI or overactive bladder, 80% had at least one other pelvic floor dysfunction. For those reporting fecal incontinence, 48% had one or more additional pelvic floor dysfunctions and 69% of the women diagnosed with POP presented with at least one other pelvic floor dysfunction (26).

Since medical and surgical interventions are often indicated, it is clear that pfm dysfunction is costly both from a financial perspective (affecting attendance and job performance) as well as an emotional and physical health outlook. Part of the challenge in creating awareness of the pfm and its importance in function lies in the ability to accurately qualitatively and quantitatively assess both function and dysfunction.

FINDING A STANDARDIZED OUTCOME MEASURE

It is important to find a standardized tool that recognizes pfm dysfunction. While some standardized tools for pfm research do exist, a thorough literature review finds the numbers of validated questionnaires limited. Furthermore, these questionnaires have been predominantly developed by specialists in urology, gynecology and gastroenterology and, understandably, have different aims and pelvic organ-specific goals compared to questions directed towards more general functions of the pelvic floor muscle and all of its responsibilities.

Until recently the gold standards for pelvic floor research included the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) (27), the King's Health Questionnaire (KHQ) (28), the Pelvic Floor Distress Inventory (PFDI) (29) and the Pelvic Floor Impact Questionnaire (PFIQ) (29). The Electronic Pelvic Floor Assessment Questionnaire (e-PAQ) (30) was the sole validated tool that encompassed all facets of pelvic floor dysfunction (urinary and bowel dysfunction, pelvic organ prolapse, pain and sexual dysfunction) until the development of the PelFIs in 2007 (1). While these are very useful tools in research, they all focus segmentally on pfm dysfunction or quality of life and, as such, no gold standard for a comprehensive tool of pfm function measurement exists.

Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ)

The PISQ is designed for assessing sexual function in women with urinary incontinence and/or pelvic organ prolapse. Its 31 items focus on behavioral/emotive, physical and partner-related domains for female sexual function. It does not allow for assessment of details regarding urinary incontinence or pelvic organ prolapse but rather seeks information on the sexual function of women who have one or both of these disorders and how this impacts their sexual function. The PISQ also accounts for quality of life assessment in women with pelvic floor dysfunction.

King's Health Questionnaire (KHQ)

The KHQ is another highly beneficial tool but focused to the field of urinary incontinence and as such is not useful for assessing details related to bowel dysfunction, pelvic organ prolapse, pelvic pain and sexual dysfunction. The KHQ offers a quality of life scale for those experiencing urinary incontinence. It is a great contributor to the field of urology but limited in its usefulness when viewing pelvic floor dysfunction as a whole.

Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaires (PFIQ)

The PFDI and PFIQ indices are more encompassing in the scope of pfm dysfunction. Historically these two questionnaires were based on the Urinary Distress Inventory (UDI) (31) and the Incontinence Impact Questionnaire (IIQ) (31) that focused on bladder dysfunction and its impact on quality of life. The PFDI and PFIQ scales added questions related to bowel dysfunction and pelvic organ prolapse so that the PFDI became an assessment tool for the domains of colorectal-anal distress, urinary distress and pelvic organ distress and the PFIQ assessed the impact of these three domains against quality of life factors. Again, these are very useful tools, however, they do not encompass the domains of pelvic pain and sexual dysfunction.

Electronic Pelvic Floor Assessment Questionnaire (e-PAQ)

While the e-PAQ fulfills the critical criteria to pelvic floor physiotherapists of being ‘all-encompassing’ to pfm dysfunction, further research is necessary to evaluate the feasibility and accessibility of the electronic tool. As it is a fairly recent contribution to the field, its utility has not yet been thoroughly analyzed in clinical practice.

Pelvic Floor Inventories Leiden (PelFIs)

The PelFIs has been shown to be valid and reliable in the Dutch language as well as being a clear and fully encompassing measuring tool directly relevant to pelvic floor physiotherapy. Its completeness in all domains of pfm dysfunction works positively in revealing pfm dysfunctions yet undiagnosed in patients seeking treatment for a single pfm dysfunction. The validation process for the English-language PelFls aims to provide an internationally usable condition-specific tool for medical professionals in assessing the comprehensive scope of pfm function. This tool will allow standardization and ensure thoroughness in history taking, leading to higher quality patient care both in the clinic and for use in future pfm research.

PURPOSE, OBJECTIVES AND HYPOTHESIS

Purpose

The purpose of the current study was to accurately and precisely evaluate the validity and reliability of the English-language Pelvic Floor Inventories Leiden (PelFIs) administered questionnaire. This promising research tool has been shown as both valid and reliable in the Dutch-language and required English validation so that it could become accessible to clinicians worldwide.

Scores on completion of the PelFIs were compared between a patient population and a control population. While the research tools reviewed may be considered gold standards for their specified area of pelvic floor research, there is no comprehensive, fully encompassing tool for measurement of all pfm function and therefore no gold standard for comparison. As such, construct validity as opposed to criterion validity was sought.

Objectives

1. To establish construct validity by quantifying the differences in prevalence of pfm dysfunction between the patient population and the control population when using the English-language PelFIs administered questionnaire.

2. To determine test-retest reliability of the English-language PelFIs in women that seek pelvic floor physiotherapy treatment for pfm dysfunction.
3. To quantify the prevalence of co-occurrence of pfm disorders within patients that present for treatment of a single pfm dysfunction. To determine correlation of pfm symptoms in domains other than the diagnosed dysfunctional domain.
4. To analyze the data and identify the most suitable and beneficial questions in gaining information toward a minimum data set to create a shorter version of the PelFIs questionnaire.

Hypotheses

1. There will be a significant difference in the prevalence of pfm dysfunction as indicated by the PelFIs scores between the patient population and the control population.
2. The English-language PelFIs will be a reliable outcome measurement tool for evaluating the presence of pfm dysfunction.
3. Many patients presenting for treatment of a single pfm dysfunction will display symptoms of co-occurring pfm dysfunctions.

METHODOLOGY

The following paragraphs provide details regarding the participants, the research evaluation tool being studied, and the overall study design and protocol.

Participants

The English-language PelFIs was administered to 50 female patients and 50 healthy female control participants. Of the 50 female patients, 25 were included in a subsample patient population necessary for the test-retest component of the study. Sample size calculation was based on the results of the Dutch-language PelFIs and consultation with the Department of Psychology (psychometrics), University of Manitoba. Ethical approval was obtained from the Health Research Ethics Board (HREB) Bannatyne Campus, University of Manitoba.

Patient Population

Females contacting the Incontinence & Pelvic Pain Clinic (IPPC) to book an initial assessment appointment, as well as those being contacted by IPPC following a physician's medical referral, were informed of the research study involving the validation of the English-language PelFIs questionnaire. Some patients may have been previously informed of this research study by their family physician or referring specialist.

The receptionist at IPPC advised patients of the details regarding the study, asked if they would be interested in participation and, if so, would they consider participating in the test-retest subset (see Appendix I: Script for Recruiting Patient Participants). All participants had the English-language PelFIs administered by a pelvic floor physiotherapist at the time of their initial assessment. This may or may not have been the same pelvic floor physiotherapist that performed the initial assessment and subsequent treatment care.

All females seeking pelvic floor physiotherapy assessment and treatment at the IPPC were considered eligible for the patient participation group regardless of which domain they experienced signs and symptoms. For example, women seeking help for symptoms of urinary incontinence were asked to participate as were women seeking treatment for pelvic pain.

Occasionally, participants who had initially agreed to complete the test-retest component of the study withdrew or were unable to attend the second administration of the questionnaire. This occurred for various reasons such as one participant unexpectedly needing to leave the country, another requiring surgery and a third participant postponing the initial assessment and declining continuation of the study. For these cases the data collected from the initial questionnaire administration was usable for comparisons between the patient population and the control population but not in the test-retest subcategory of patients.

Control Population

Female individuals who had never sought medical attention or used (or were currently using) medications for bladder, bowel, pelvic pain or sexual issues related to pfm dysfunction were qualified to participate in the control population. Volunteers were recruited by various means such as advertising posters (see Appendix II: Advertising Poster) and word of mouth. Women were informed of the details of the research study by a pelvic floor physiotherapist and asked to participate. They were shown the IPPC routine questionnaire for review so that they would have an understanding of the content and sensitive nature of the PelFIs questions before committing to the study. This ensured that both groups had been exposed to the same information before administration of the research tool. The English-language PelFIs was administered to the volunteers by the physiotherapist.

Inclusion/Exclusion Criteria

Common referral symptoms to IPPC include urinary incontinence, bladder urgency, bladder frequency, incomplete bladder emptying, bladder pain, bowel incontinence, bowel urgency, bowel frequency, incomplete bowel emptying, chronic diarrhea, chronic constipation, rectal pain, perineal or vaginal pain, sexual pain, and pelvic organ prolapse of the bladder, uterus, or bowel. Those female patients booking assessment for pfm exercise instruction but not experiencing symptoms of pfm dysfunction were not considered appropriate for the study and therefore not asked to

participate. Participants were also excluded if they were not fluent in the English language.

Confidentiality of the English-language PelFIs

The questionnaire maintains confidentiality by labeling with a numeric system and date of birth. At no point on the questionnaire were participants asked to record their name. Informed consent forms were collected and labeled with reference coding. Participant names and the corresponding reference code number were maintained on the Confidential Participant Code Form (Patients) (see Appendix IV) and Confidential Participant Code Form (Control Participants) respectively (see Appendix V). Those participants agreeing to partake in the subsample for test-retest reliability were also recorded on the Confidential Participant Code Form (Patients).

Research Evaluation Tool

The Dutch-language PelFIs consisted of an 83-item instrument with nine separate domains measured. During the validation of the Dutch-language PelFIs, it was noted that certain domains did not sufficiently investigate all corresponding symptoms. To correct this deficiency items were added into these domains on the English-language PelFIs.

Domains of the English-language PelFIs

The English-language PelFIs (see Appendix III: English-Language PelFIs) consists of nine domains with additional questions producing a 149-item instrument. Of the 149 questions, the initial 50 constitute medical intake evaluation and 14 Quality of Life questions are interspersed throughout the document. The remaining 85 questions fall under specific domains of pfm dysfunction. The domains consist of questions that have been grouped together according to clinical relevance;

- Domain Micturition Pattern (17 question items)
- Domain Urinary Incontinence (8 question items)
- Domain Obstructive Micturition (10 question items)
- Domain Pelvic Organ Prolapse (6 question items)
- Domain Defecation Pattern (9 question items)
- Domain Fecal Incontinence (16 question items)
- Domain Constipation (5 question items)
- Domain Pelvic Floor Pain (7 question items)
- Domain Sexual Dysfunction (7 question items)

Question Format

The English-language PelFIs consists of several formats of questioning. There are some 'fill in the blank' questions, however, the majority of questions follow a Likert Scale format for summative analysis (32). Selections vary throughout the measurement tool offering between 2 and 7 selection choices, and changing between 'yes/no' scales,

‘never, seldom, sometimes, regularly, always’ scales and scales offering numerical values such as ‘2-4 x per day, 5-7 x per day, 8-10 x per day, more than 10x per day’. Some of the ‘Likert-style’ questions vary from true form by allowing the selection of ‘other’ followed by ‘please indicate’ and allow space for explanation (33).

Interspersed throughout the form are visual analogue scale questions for participants to complete by crossing the line in the position best reflecting their feeling toward a symptom at that particular moment. Those were the only questions physically completed by the participant as all other items were asked and recorded by the administrating pelvic floor physiotherapist.

Question Content

The first 50 questions pertain to overall health status, reason for seeking medical attention and duration of complaints (for the treatment population), medications and past medical and surgical interventions, occupation and status, marital and living status, dietary factors such as alcohol and fluid/fibre consumption, tobacco use, physical activity and obstetrical history.

Following this is the domain pelvic organ prolapse where questions 51 through 56 relate to decreased support and ‘sagging’ of perineum. The domain for micturition encompasses questions 57 through 73 and details related to diurnal and nocturnal voiding patterns to detect urgency and frequency syndromes.

From questions 74 to 81 the domain for urinary incontinence is filled by addressing symptoms of loss of bladder control. The domain for obstructive micturition

covers items 82 through 91 to capture data on incomplete bladder emptying, chronicity of urinary tract infection, childhood nocturnal enuresis, and pad or catheter usage.

The domain Defecation Pattern consists of questions 94 to 102 and details bowel emptying habits as well as consistency of stool. This leads into questions 103 to 118 in the domain for fecal incontinence relating to loss of bowel control, bowel urgency, anal tissue breakdown, hemorrhoids and diet, medication and pad usage. The domain for constipation covers questions 121 to 125 for description of bowel emptying habits and the domain for pelvic floor pain, items 128 to 134 assesses vaginal, rectal, abdominal and perineal pain as well as pain associated with sexual intercourse.

The final domain, Sexual Dysfunction, uses questions 137 to 143 to reveal sexual dysfunction. Quality of life issues of bladder and bowel dysfunction and pelvic pain at home, work or during leisure activities, are identified, as well as allowing for past abuse issues to be revealed and asking the participants if they have had or would like to receive help in dealing with this, are assessed sporadically throughout the research tool in questions 92, 93, 119, 120, 126, 127, 135, 136, and finally 144 through 149.

Adaptations to the PelFIs

When translating a questionnaire it is vital to address cultural adaptations in addition to direct linguistic application. An example of this is noted in question 65; "How do you urinate?

a. sitting
b. 'hanging'

c. at home sitting, elsewhere ‘hanging’.

For the English questionnaire, it was important to exchange the word ‘hover’ with the Dutch choice of ‘hanging’ as this would not be a recognizable term in North America. Therefore in the English-language PelFIs, question 65 appears as below.

“How do you urinate?”

a. sitting
b. hovering
c. at home sitting, elsewhere hovering.

Other examples of the language distinctions between the Dutch-language PelFIs and the English-language PelFIs occur in question 133 asking “Do you ever have pain around the ischii?” in the Netherland study being replaced with “Do you ever have pain around your sit bones?” in our questionnaire. The word ‘cystitis’ was used twice in the Dutch questions and replaced with our commonly used term, ‘urinary tract infection’. Small changes were also made to make the English-language PelFIs more user-friendly by simply rephrasing in North American styling and using terms likes ‘glasses’ and ‘cups’ versus the Dutch choice of ‘beaker’.

Relevance of Questions for Statistical Analysis

In addition to altering some of the questions when creating the English-language PelFIs, it was determined at the start of the study design process that not all of the 149 items in the questionnaire would be appropriate to clinical use and as such would not be included in the statistical analysis. The first 50 items were not needed for statistical analysis of symptoms as they pertain specifically to medical intake evaluation and not

symptoms or complaints related to pelvic floor function. However, these intake questions were useful in determining type and number of medical concerns that led patients to seek medical attention and were used in evaluation of potential co-occurrence of pelvic floor dysfunctions. The intake questions were also useful for demographic comparisons between the patients and control participants for equality of variables such as age and obstetrical/gynecological histories and general medical background.

Questions numbered 59, 60, 69, 141-143, and 146-149 (10 of the 149 questions) were not used for statistical analysis as they do not pertain specifically to clinical treatment in North America nor do not directly relate to symptoms or complaints associated with pelvic floor function. Of the 149 items recorded, 89 items generated data useful to statistical analysis of symptoms, and 50 items were used for demographic analysis at the completion of collection.

Study Design

The research investigation followed a survey design. Participants were asked to complete the 149-item questionnaire that was administered by a pelvic floor physiotherapist. The questionnaire was modified from its original form in the Dutch-language for increased strength in validity as well as to accommodate for cultural differences. The two study groups consisted of patient participants and control participants. The protocol was approved by the Health Research Ethics Board (HREB), Bannatyne Campus, University of Manitoba. All study data of the patient population was collected at IPPC in the Medical Arts Building, downtown Winnipeg. For the

convenience of the volunteers in the control group, data collection took place at various locations including IPPC and the Bannatyne Campus, University of Manitoba.

Informed Consent Documentation

All participants in the study were required to sign informed consent documentation (see Appendix VI: Informed Consent Form) before administration of the questionnaire. Before signing the document, each individual was asked to read the informed consent form thoroughly and initial each page at the bottom right-hand corner indicating that each page has been noted and read. They were also encouraged to ask any questions or discuss any concerns with the pelvic floor physiotherapist present.

Participants from the patient population were reminded that they could decline to be a part of the study at any time and assured that there would be no consequence to their assessment and treatment at the clinic. As one of the benefits to participation, patients were advised that the questionnaire allowed their pelvic floor physiotherapist a complete picture of the function of their pfm in all aspects thus granting an even more thorough investigation to their individual dysfunction and leading to a higher quality of care for themselves currently, and in future, to all patients.

Participants of the control population were reminded that, while they may or may not directly benefit from volunteering in this study, their willingness to take part in the study would benefit those suffering with pfm dysfunction worldwide.

Protocol

The English-language PelFIs was read to the patient by a qualified pelvic floor physiotherapist, as this is an administered questionnaire. Participant responses were then recorded by the therapist with the exception of participants marking a line on the visual analogue scale for necessary items. Questions were asked as closely as possible to written script and physiotherapists were encouraged to avoid additional explanations or comments. If patients did not understand the medical terminology, they were instructed to answer the question to the best of their knowledge. Upon completion of the 149-item questionnaire, the commitment to the research study was fulfilled and assessment and treatment for the patient commenced.

Those patients who were willing to participate in the test-retest component were asked to present to the clinic a minimum of two weeks prior to their initial assessment. The English-language PelFIs was administered by a pelvic floor physiotherapist following the format noted above. To fulfill the 'retest' component, this patient subset completed the same questionnaire, administered by a different pelvic floor physiotherapist, at least two weeks later but still before beginning treatment. Before beginning the second administration, participants were asked if they had done anything differently in regard to pelvic floor health, during the period between the two questionnaires. If there were any altered behaviors, the physiotherapist was instructed to note the changes on the document. Upon completion of the second administration of the English-language PelFIs, the patient subset group had fulfilled the research study commitment and assessment and treatment commenced. To compensate the 25 participants for their visit to the clinic solely for the research study, parking was

validated and these test-retest participants received an educational book related to female urinary incontinence and pelvic floor muscle health (valued at $29.99). Parking validation took place following completion of the first administration of the PelFIs however, the educational book was not given to the patient until completion of the second administration of the PelFIs to prevent this informational material from altering responses at time-two of testing.

The English-language PelFIs was also read to the control participants by a qualified pelvic floor physiotherapist, at either the IPPC or off-site, depending on where was more convenient. The PelFIs was administered and recorded in the same manner to the patient participants. Upon completion of the 149-item questionnaire, participant commitment to the research study was fulfilled. As pfm dysfunction is highly prevalent and often unknown to patients and therefore may remain undiagnosed for many years, control participants were encouraged by the physiotherapist to discuss any concerns or questions they may have following the administration of the questionnaire, either with the physiotherapist or their physician. Additionally, the control population was given a listing of available resources and information regarding pelvic floor dysfunction and encouraged to contact the resource centres if they had any concerns or wanted further information.

All participants in the study were thanked for their contribution to the outcome measures tool for the promotion of pelvic floor function research on an international scale.

Collection and Storage of Documentation

All information collected from participants was accessible and available only to the research staff and was kept strictly confidential. Media containing sensitive information is being stored in a locked filing cabinet, or stored on a password-protected computer. Data was reported in aggregate form. Names of participants appear only on the consent form and not on the questionnaires. Questionnaires and consent forms are being stored separately in a locked cabinet. Questionnaires maintain complete anonymity and rely on tracking numbers for reference. Anonymized data has been copied and sent to the original Dutch-language PelFIs researchers and its receipt confirmed. All consent forms and confidential coding forms containing signatures and names remain physically secured on-site. After a period of seven years, the documents will be destroyed by documentation shredding and deletion of computer files.

Data Analysis

Data was analyzed using SPSS software**.** Items of each domain were summed and calculated into a score where the higher scores indicate the increasing prevalence of symptoms.

Validity

As there is no true gold standard measuring tool for pelvic floor function, construct validity as opposed to criterion validity was sought. Construct validity between the domains of the patient population and the control population was assessed using Discriminant Analysis. This method grants comparison of the complete patient population (n=50) sum of scores and the complete control population (n=50) sum of scores, even when groups possess multiple variables as these groups do in having 9 separate domains. Findings of between group differences where $p<0.05$ were considered significant. Construct validity was further analyzed by comparing each patient domain with the corresponding control domain and independent t-testing was used with $p<0.05$ considered significant.

Content validity was attained by seeking advice from a variety of experts in the field appropriate to the domain. Medical experts were asked to complete the evaluation questions relevant to their specialty of practice as well as the document as a whole. For example, urologists were asked to assess the questions within the domains for micturition pattern, urinary incontinence and obstructive micturition. Gynecologists were asked to evaluate the questions within the domains for pelvic organ prolapse, pelvic floor pain and sexual function. Urogynecologists assessed all domains relating to urology and gynecology. Gastroenterologists and/or colorectal specialists were asked to review the questions with the domains for defecation pattern, fecal incontinence and constipation. Respondents were encouraged to evaluate as many of the domains as they felt comfortable reviewing. The content validity evaluation pages (see Appendix VII: Content Validity Evaluation), printed on blue paper for easier distinction, were inserted

into the PelFIs following each section. Each evaluation page consisted of four Likert format questions regarding relevance, accuracy, omissions and overall impression of the PelFIs questions. These same four Likert questions were also asked in regard to the document as a whole. An area for comments was also included.

Reliability

Test-retest reliability is necessary to show stability of an instrument over time. The English-language PelFIs was administered to twenty-five patient volunteers a minimum of two weeks prior to their scheduled initial assessment and again at their initial assessment, before treatment commenced. This subsample data was analyzed for association between time-one to time-two using Intraclass Correlation (ICC) with the acceptable coefficient for group differences being ICC=0.70. The associations between time-one to time-two patient responses were analyzed for detection of correlation between the document as a whole, and also individual comparisons were made between each of the 9 patient domains separately. To prevent concerns with inflation of values, single measures were used in the SPSS analysis rather than average measures (i.e. individual scores were entered not sums of scores).

Internal consistency was determined by correlating items within domains. Each of the 9 domains has 5 to 17 question items, depending on the domain. Pearson's Correlation was used to detect differences between domains, with the acceptable coefficient for group differences being 0.70. In addition to the inter-correlations, Cronbach's alpha was used to assess internal consistency of the scales. A high alpha value would reflect that all items co-vary to the same degree, with alpha values of 0.70

or greater considered significant. This test allows us to identify items within the domains that cause a decrease in alpha value. By determining these items, the domain may be 'trimmed' by removing the less helpful questions and thereby increasing the alpha value.

Finally, to identify items that are relatively more informative than other items, nonparametric tests were performed, with Wilcoxon Rank Sum testing used for the ordinal-level data questions and Chi-Square testing used for the discreet-level data questions. The patient responses were analyzed against the control responses for individual questions. For significance, a critical value of $p<0.05$ was used for both data level questions. If significance was found then the item was determined to be highly beneficial. If no significance was noted, then the item was considered to not distinguish between patients and control participants and may be dropped in future development of a shorter version PelFIs.

RESULTS

Comparable Groups of Participants

It is vital to ensure that the patient population and control populations were comparable groups of women who differ only in regard to the inclusion and exclusion criteria that defined their group. For example, the patient population (n=50) had an age range of 24-82 years with a mean of 52.86 ± 13.32 years and this was compared to the control population (n=50) age range of 21-83 years with a mean age of 48.78 ± 16.52 years. Overall, there is similarity in age between the two groups.

Table 1 illustrates the characteristics between the patient and control participants. There were no significant differences between the groups in demographic characteristic comparisons of age, work status and sexual partner. Also, no significant differences between the two groups were noted in lifestyle habits such as current and past smoking status, alcohol consumption, caffeinated coffee and tea consumption and caffeinated soda consumption. Dietary factors, such as regularity in eating habits, fiber intake in diet and fluid intake, were also compared with no significant differences noted. No significant differences were noted in some of the health criteria tested, such as height, weight and BMI of participants, care of a cardiologist, endocrinologist, oncologist, internist, surgeon, gastroenterologist or other health specialists, presence of other medical conditions such as diabetes and heart and lung conditions. There were also no significant differences noted in gynecologic and obstetrical histories of the two groups, for the categories related to number of pregnancies, weights of babies birthed,

vaginal births, cesarean section births, use of vacuum extraction, forceps and induction, superficial and severe tearing of the perineum, and menstruation status.

Some of the data showing no significant differences between the patient and control participants was surprising, as differences between the groups would have been predicted. Examples of this include smoking and beverage consumption status between the groups, as smoking and caffeine intake tend to irritate the bladder and often produce symptoms of bladder frequency and urgency. Table 1 details these results. It was also surprising that no significant differences were noted between the levels of fluid intake for the two groups, as this also can directly impact bladder and bowel function. Table 1 details the fluid intake levels of the two groups as well as summarizing the unexpected similarities between the birthing histories of both groups (also detailed in figure 1), as pregnancy and delivery directly impact the pfm. Interestingly, no significant differences were found between the numbers of pregnancies, birth weights of the participants' babies, and most medical interventions such as mode of delivery, prevalence of severe and superficial perineal tearing, and the use of forceps and vacuum extraction, for the two groups. While the overall number of pregnancies within both groups was comparable, it should be noted that the control group more than doubled the patient population in the category of 'never having been pregnant' and that the patients doubled the control participants in the 'four or more pregnancies' category.

There were however, significant findings in overall health status between the two groups, with a Mantel-Haenszel Chi-Squared value=5.5818, p=0.0181. Of the control participants, 70% reported that their health was 'very good' to 'excellent', compared to only 50% of the patients rating their health so positively. Only 4% of the control

participants rated their health as ‘moderately good’ or ‘poor’, where as 22% of the patients reported these levels of health status. Figure 2 further details the overall differences found in health status of the patients versus the control participants. As well, when comparing the use of medical specialists, highly significant findings were found with a Chi-Squared value of 12.7033, p=0.0004, as noted in Table 1 and illustrated Figure 3. Specifically, the care of gynecology was a discipline that showed significant findings, as Chi-Squared testing produced a value of 5.2632, p=0.0218. Regarding specific medical conditions, significance was noted for vascular conditions, Chi-Squared=9.7561, p=0.0018, and the presence of back pain was highly significant, with Chi-Squared=11.1111, p=0.0009. Figure 4 further illustrates these findings. Overall, the presence of other major medical illness or disorders was also highly significant, with Chi-Squared=18.2307, $p<0.0001$. When episiotomy use was compared between the patient population and the control population, significant findings of Chi-Squared=8.3580, p=0.0392 were found. These findings are further illustrated in Figure 1. The use of episiotomy was found to be greater than 1.5 times higher in patients versus the control participants. Finally, Table 1 also notes the highly significant finding that menopausal symptoms are of greater concern within the patient population compared to the control population, as Chi-Squared=21.5686, $p<0.0001$.

Figure 5 details the comparison between the patient and the control participants with regard to menstruation status. It is notable that while the two groups were very similar in the numbers still menstruating, and also in numbers of women in menopause, their experience within these categories differ dramatically. Of the menstruating women, the patients reported much more irregularity in their menstrual cycles, compared to the

control participants. For the menopausal women, the patients reported significantly higher ($p<0.0001$) concerns with menopause-related symptoms, than did the menopausal control participants.

When surgical history was compared between the patient population and the control population, many differences were noted, as detailed in Table 1. The two groups showed notable differences within the 'urologic surgery', 'general surgery' and 'gynecologic surgery' categories, and less notable differences within the category 'orthopedic surgery'. The categories 'thoracic surgery', 'no surgery' and 'mean total surgery' were all similarly matched with the patient surgical mean=1.64 and the surgical mean for the control participants being 1.08. Interestingly, every participant regardless of group, had previously undergone surgery.

The activity level of the two groups can be found detailed in Table 1. Activity episodes of a minimum of 30-minutes of exercise such as walking, gardening, swimming, etc. were tallied. The two groups showed differences throughout all categories except for the '1 time per week' category. The control participants were more highly represented in the '2 to 4 times per week' and 'daily' activity categories while the patients were more highly represented in the 'never' and 'irregularly' exercise categories. Overall, the patients were shown to be somewhat less consistent with physical activity than the control participants.

Another differing factor was found when comparing the length of pushing during the labours of the two groups. Table 1 details these findings, with control participants having notably shorter durations of pushing during labour, when compared to the patient

group. The two groups showed significant differences within the '15 minutes' category with 18 control participants filling this category, compared to only 10 patients, as well as the 'greater than 60 minutes' category that held 12 patients compared to 6 control participants. Less notable differences were found within the categories '30 minutes', '45 minutes' and '60 minutes'. Overall, a dramatic difference was noted on both ends of the spectrum. The control participants reported 26 women, compared to 10 patients, having pushed 30 minutes or less, and only 8 control participants, compared to 19 patients, pushed for 45 minutes or more during their labours.

The remaining difference noted between the patient and the control population related to use of medication. The pharmaceutical intake of the participants was analyzed using parametric and nonparametric testing, as appropriate, however, the results were not included in Table 1 as data counts were too low to produce valid testing. They are however, notable findings and included in Figure 6. The two groups showed notable differences within the use of 'bladder medication', 'anti-depressants', 'pain medication', 'contraception', 'other medication' and 'no medication' categories and less notable differences within the categories 'lung medication' and 'heart medication', as detailed in Figure 6. The category 'bowel medication' was similarly matched between the patients and the control participants. The overall medication consumption was found significantly higher ($p<0.02$) for the patient population when compared to the control population with the exception of the category 'contraception' which was notably higher for the control population. Also noteworthy, is that over twice as many control participants reported no use of medication, compared to the patients.

While many differences were noted between the comparison of the patient population and the control population, the majority of characteristics compared found no significant differences, as seen in Table 1. For the purpose of our research, the control group and the patient group are found to be appropriately similar for comparison.

Comparing Patients to the Control Participants

To note dysfunction within participants it is necessary to define acceptable parameters within the domains. For several domains acknowledgement of the presence of symptoms by participants, such as experiencing loss of bladder or bowel control qualifies as urinary or fecal incontinence respectively, while others necessitate qualitative criteria such as domains Micturition Pattern and Defecation Pattern. For the purpose of the English-language PelFIs questionnaire, the following details the criteria used to evaluate the nine domains.

Domain Micturition Pattern

This domain evaluates the frequency of urination, both day and night, as well as the presence of bladder urgency and the ability to delay the need to void. The developers of the Dutch-language and English-language questionnaires have followed the commonly adhered to International Continence Society definition of voiding 5 to 9 times per day (allowing for variation in fluid intake) as being within normal parameters. Participants reporting daily voiding frequency of 2 to 4 times are considered to have a dysfunctional micturition pattern of a decreased frequency of voiding, whereas those

reporting more than 10 voids per day are determined to have a dysfunctional micturition pattern consisting of an increased frequency of voiding.

The results of the completed questionnaires revealed that of the n=50 patients studied, 5 experienced symptoms of decreased daytime urinary frequency and 1 of increased daytime urinary frequency. Of the n=50 control participants, 7 experienced decreased daytime urinary frequency and 9 displayed symptoms of increased frequency of daytime voiding. Table 2 illustrates these symptoms in the bladder domains. It was an interesting finding to have 14% of the control participants compared to only 10% of the patients having voiding frequencies less than the acceptable criteria. Noting that 18% of the control participants and only 2% of the patients experienced unacceptably high numbers of daily voids, was even more unexpected as patients tend to void frequently to avoid bladder irritation, discomfort or leakage.

Nocturnal, or nightly, voids were also evaluated for detection of abnormal outcomes. Nocturia is the need to wake from sleep one or more times due to the need to void, as defined by the International Continence Society. The English-language PelFIs has again followed these guidelines for the determination of nocturia. The presence of symptoms of nocturia is considered a dysfunction within the domain Micturition Pattern.

Review of the data shows that 28 of the patients, and 27 of the control participants, voided 1-2 times per night and 8 patients and 2 control participants voided 3-4 times per night. Additionally, one patient reported the need to void greater than 4 times each night (see Table 2). Thus 56% of patients and 54% of control participants

displayed significant and virtually equal dysfunctions with waking to void 1 to 2 times per night. Regarding nocturnal urinary frequency of three or more voids, 18% of patients suffered with these symptoms compared to only 4% of the control participants.

The presence of abnormal bladder urgency was an additional symptom of a dysfunctional micturition pattern. Abnormal bladder urgency is the feeling of needing to void occurring too frequently i.e. less than every 2 to 4 hours, or not often enough (greater than the acceptable 2 to 4 hour window). Also, bladder urgency that cannot be adequately delayed and therefore interferes with activities of daily living was also considered a dysfunctional voiding pattern.

Analysis of responses to bladder urgency questions revealed that 1 patient and zero control participants suffered with constant feelings of needing to void. Twenty-five patients and 10 control participants reported responses of urgency occurring less than every 2 hours. A delay in feelings of bladder urgency, were noted in 3 patients compared to 5 control participants (see Table 2). The notable difference between patients and control participants in this category is that 50% of the patients experienced bladder urgency less than every 2 hours compared to 20% of the control participants showing a 2.5 times increase for patients.

Table 3. Poor Toileting Biomechanics, lists 9 patients and 13 control participants as reporting to sit to void when at home however hover over the toilet when elsewhere. Less patients (18%) than control participants (26%) displayed this poor posture during voiding.

Domain Urinary Incontinence

For this domain, participants were asked if they ever experience urinary incontinence. Those who responded 'yes' were considered to have dysfunction within this domain. Further details regarding amounts, frequency and positions during leakage were also evaluated and reported in Table 2. Forty-three of the 50 patients reported symptoms of urinary incontinence. Of the 50 control participants, 28 (56%) also described experiences with urinary incontinence. While this seems highly representative, female urinary incontinence is very common and this figure it is still significantly lower than the finding of 86% of patients experiencing loss of bladder control.

Domain Obstructive Micturition

Those participants reporting the feeling of not having completely emptied their bladder following voiding, were considered to have a dysfunction of obstructive micturition. As well, those participants that noted post-void dribbling of urine upon rising from the toilet were also considered positive for dysfunction within domain Obstructive Micturition. Pain with urination, as well as, history of urinary tract infections were also notable symptoms evaluated within this domain. These results can also be found in Table 2.

With regard to feelings of incomplete bladder emptying following voiding, 21 patients versus 8 control participants reported experiencing this symptom. Furthermore, 17 patients compared to 14 control participants noted urinary dribbling upon rising from

voiding. Patients (42%) experienced feelings of incomplete bladder emptying over 2.5 times more frequently than the control participants (16%). Dribbling urine with rising from the toilet, was experienced by both groups, however, patients (34%) were still more highly represented than the control participants (28%).

Domain Defecation Pattern

For this domain, the frequency of participants' bowel movements was evaluated with the Rome criteria of greater than three bowel movements per day and less than 3 bowel movements per week considered abnormal. The feeling of bowel urgency, consistency of stool and sensations of elimination were also evaluated.

Table 4 documents the symptoms noted within domains Defecation Pattern, Constipation and Fecal Incontinence. For the domain Defecation Pattern, 1 patient as well as 1 control participant reported having only a single bowel movement each week. Another notable finding in this table is that 3 patients and 1 control participant chose the 'other' category. Evaluation of reasons given for this selection indicate that 1 of the 3 patients has an iliostomy bag to collect stool, while the remaining 2 report large fluctuations in frequency of bowel movements. The single control choosing the 'other' category, reported 5 bowel movements per day. Overall the 2% of both patients and control participants reporting a single bowel movement per week, as well as the 6% of patients compared to 2% of control participants selecting 'other', were considered to display dysfunction within the domain Defecation Pattern.

Domain Fecal Incontinence

Table 4 also illustrates dysfunction within the domain Fecal Incontinence in terms of frequency of occurrence, position and activity during loss of stool, presence of mucus, pad usage and sensation of bowel incontinence. Sixteen patients and 3 control participants reported symptoms of fecal incontinence. The percentage of patients experiencing dysfunction in domain Fecal Incontinence (32%) is over five times greater than the 6% found dysfunctional in the control participants.

Domain Constipation

The feeling of completely emptying the bowels with evacuation was the assessment tool for constipation. Feeling that the bowels were not fully emptied following defecation, was considered a symptom of constipation. Additionally, the need to strain with bowel movements and consistency of stool were also assessed and presented in Table 4. Six of the 50 patients and 3 of the 50 control participants reported that they never, or seldom, feel that they have fully emptied their bowels following defecation. Also, 11 patients and 9 control participants feel that they only sometimes fully empty their bowels. Seldom or never feeling that their bowels have been completely eliminated affected twice the number of patients (12%) compared to the control participants (6%). Constipation of a lesser intensity was reported in 22% of patients compared to 18% of the control participants. While this comparison is more closely matched, patients still out-number the control participants for domain Constipation.

Domain Pelvic Organ Prolapse

Participants experiencing a feeling of pressure or heaviness within their vagina or perineum that increases throughout the day or with bowel movements were considered to have symptoms of pelvic organ prolapse (POP). Additionally, participants that visualized tissue coming out of their vagina or anus, or had felt this tissue with their fingers were also considered positive for POP.

Table 5. Symptoms of Pelvic Organ Prolapse, Pelvic Floor Pain and Sexual Dysfunction, details the participants' responses regarding symptoms of POP. Fourteen patients and 4 control participants responded that they 'seldom to sometimes' note the presence of POP symptoms, whereas, 5 patients and 0 control participants report 'regular to constant' presence of POP symptoms. Thus the domain Pelvic Organ Prolapse is more highly represented in patients compared to control participants.

Domain Pelvic Floor Pain

Participants were questioned on the presence of pelvic pain in several locations. Cramping or pain around the anus, pain between the vagina and anus, coccyx (tailbone) pain and ischial tuberosity pain (pain near the sit bones), were all evaluated. Reports of pain in any of these areas were considered symptoms of dysfunction within this domain and are presented in Table 5. Overall, patients reported significantly more symptoms of pelvic floor pain than the control participants. Anal cramping was noted by 13 patients and 3 control participants. The symptoms of perineal pain, or pain between the vagina and anus, was reported by 12 patients versus 3 control participants. Coccyx pain was

experienced by 17 patients and 10 control participants, and ischial tuberosity pain, was felt by 16 patients and 8 control participants.

Several participants showed pain symptoms in more than one area with the highest noted combination being coccyx and ischial tuberosity pain reported for 5 patients and 4 control participants. Notably, 4 patients reported pain in all four areas followed by the presence of both anal cramping and perineal pain reported by 3 patients and 1 control. For the combination of perineal, coccyx and ischial tuberosity pain, symptoms were reported by 2 patients and 1 control participant. The remaining multiple pain area categories were, 1 patient reporting anal cramping with tailbone and sit bone pain, and 1 control experiencing both rectal spasm and sit bone pain.

Domain Sexual Dysfunction

For this domain participants were asked if they experienced discomfort or pain during sexual intercourse. They were also queried as to whether the pain was experienced on penetration or deep within. Bladder or bowel incontinence during intercourse or orgasm, risk of urinary tract infection with intercourse, as well as satisfaction with intercourse were also evaluated. Participants reporting symptoms during sexual intercourse were considered to be experiencing dysfunction within this domain.

Over half (26 of the 50) of the patients reported pain with sexual intercourse compared to 12 of the 50 control participants (see Table 5). Upon further investigation, 18 patients and 10 control participants reported pain on penetration with intercourse,

while 24 patients compared to 6 control participants reported pain deep within, during intercourse. Many participants reported both symptoms, pain with penetration as well as pain deep within, during intercourse.

Overall Presence of PFM Dysfunction Noted

Figure 8 summarizes the complete findings of pfm dysfunctions. For the three bladder domains, 38 patients (76%) compared to 21 control participants (42%) noted dysfunction in the domain Micturition Pattern, 43 patients (86%) and 28 control participants (56%) experienced dysfunction within domain Urinary Incontinence, and domain Obstructive Micturition was found dysfunctional for 28 patients (56%) and 10 control participants (20%). For the three bowel domains, 10 patients (20%) and 6 control participants (12%) noted dysfunction within the domain Defecation Pattern, 16 patients (32%) versus 3 control participants (6%) suffered with dysfunction in domain Fecal Incontinence, and domain Constipation was found dysfunctional for 17 patients (34%) and 12 control participants (24%). Finally, for the remaining three domains, 23 patients (46%) and 6 control participants (12%) reported dysfunction for domain POP, 30 patients (60%) and 16 control participants (32%) suffered with dysfunction in domain Pelvic Floor Pain, and domain Sexual Dysfunction was evident for symptoms in 26 patients (52%) and 12 control participants (24%).

Patients were found to have more dysfunction in every one of the nine domains. The most similarity between the patient and control groups was noted within the domains Urinary Incontinence, Defecation Pattern and Constipation, however these showed approximately 1.5 times as many patients with dysfunction compared to control

participants. The most dramatic differences between the two groups was noted in the domains Obstructive Micturition, Pelvic Organ Prolapse and Fecal Incontinence, with patients numbering control participants by multiples of 3, 4 and 5 respectively.

Co-occurrence of PFM Disorders

The third objective of this research study was to quantify the co-occurrence of pfm disorders within those patients that present for a single pfm dysfunction. Table 6. Number of Domains Patients Experienced Dysfunction illustrates these details. Of the 50 patients, 47 had a single pfm disorder for which they sought treatment and the remaining 3 patients requested treatment for two pfm disorders. All 50 patients, 100%, indicated symptoms in domains other than the domain or domains, for which medical treatment was sought. For the 47 patients reporting a single dysfunctional domain, disorders were noted in between 2 to 9 domains. For the 3 patients presenting for treatment in two domains, dysfunction was noted in 3, 6 and 7 domains respectively. It should be noted that 5 of the 50 patients showed dysfunctions in domains that are often related or directly connected. For example, it is understandable that the patients presenting with urinary incontinence also have symptoms in domain Micturition Pattern and/or domain Obstructive Micturition. The remaining 45 of the 50 patients however, noted dysfunctions in varying domains such as patients presenting with urinary incontinence also experiencing symptoms in bowel domains and pain domains. Overall, 70% of the patients experienced dysfunction in 4 or more domains. One of the patients reported dysfunction in every one of the nine domains possible. Co-occurrence of pfm dysfunctions within the patient population has been shown with dramatic results.

It should also be noted that of the 50 control participants, only 3 showed no dysfunction in any of the nine domains. Table 7 illustrates PFM Dysfunctions Detected in Control participants. Overall, 94% of the control participants experienced some symptoms of pfm dysfunction. Of the 3 'perfect' control participants, 2 displayed poor toileting biomechanics as 1 reported straining 'seldom to sometimes' and the other strained 'regularly to always', during bowel movements. Having said that, these two individuals displayed no symptoms of pfm dysfunction. The remaining single control representative was found to be both symptom-free as well as displayed proper toileting postures and habits. Overall, 20% of the control participants displayed dysfunction within a single domain, 22% suffered with dysfunction of 2 domains, 30% reported symptoms in 3 domains, 16% had dysfunction within 4 domains, and 6% of the control participants experienced dysfunction within 5 of the 9 domains (see Table 7. PFM Dysfunctions Detected in Control participants).

Construct Validity

Construct validity between the domains of the patient population and the control population was assessed using Discriminant Analysis. Results are presented in Table 8. Findings were very significant with Hotelling-Lawley Trace $F=10.83$ ($p<0.0001$), supporting the first hypothesis of this research study as it shows construct validity of the English-language PelFIs. As anticipated, while the presence of pfm dysfunction within the control population was anticipated, significant differences between the two populations were shown.

Construct validity was further analyzed by comparing each patient domain with the corresponding control domain. All domain comparisons were found to be very significant with $p<0.0001$ for all domains with the exception of domain Defecation Pattern, where significance is seen with $p=0.0048$. This further supports construct validity within the questionnaire.

Content Validity

Eight experts consisting of one urologist, one urogynecologist, one gynecologist, two colorectal surgeons and three sexual medicine/pelvic pain specialists completed the content validity questionnaire for assessment of the English-language PelFIs. All of the eight experts completed the four Likert questions pertaining to the Medical Intake portion of the questionnaire, domain Defecation Pattern, domain Fecal Incontinence, domain Constipation, domain Pelvic Floor Pain and the document as a whole. Seven of the experts completed evaluation of domains Micturition Pattern, Urinary Incontinence, Obstruction Micturition, and Sexual Dysfunction with one colorectal surgeon choosing to omit these domains, as they were not relevant to his specialty of practice. Six of the experts completed the evaluation of domain Pelvic Organ Prolapse with the urologist and gynecologist choosing to omit these sections, as they were not relevant to their clinical practice. Table 9 shows detailed results of the expert responses. Each of the nine domains plus the medical intake portion and the document as a whole were evaluated on relevance, accuracy and omissions of questions within the section as well as the section overall. These four questions were evaluated on a scale of 0 to 4 with 0

reflection numerous concerns, 1 for several concerns, 2 for a few concerns, 3 corresponding to a single concern and 4 being no concerns with the questions noted.

The lowest evaluation scores were noted in the Medical Intake portion of the document with a mean score of 2.594 and a perfect score being 4.000. The 4 areas of measurement within this section ranged between 2.500 for 'accuracy of questions' (falling midpoint between a score of 2 reflecting 'a few concerns with accuracy' and a score of 3 correlating with 'a single area of concern with accuracy') to 2.875 for 'relevance of questions' (with a score of 2 reflecting the relevance of questions rating of 'satisfactory' and 3 being 'very relevant').

The PelFIs as a whole document as well as the domain Sexual Dysfunction, both received mean scores of 2.750. The remaining eight domains faired more positively under expert scrutiny producing mean scores ranging between 3.000 (domain Pelvic Organ Prolapse) and 3.781 (domain Fecal Incontinence). Grouping the nine domains into domains related to the bladder organ (i.e. domain Micturition Pattern grouped with domain Urinary Incontinence and domain Obstructive Micturition), domains related to the bowel organ (i.e. domain Defecation Pattern grouped with domain Fecal Incontinence and domain Constipation) and domains related to discomfort and pain dysfunctions (i.e. domain Pelvic Organ Prolapse grouped with domain Pelvic Floor Pain and domain Sexual Dysfunction), the bowel domains were rated highest (mean=3.708) followed by the bladder domains (mean=3.512) and finally the discomfort and pain domains (mean=3.010), when comparing overall average domain scores.

Test Retest Reliability

The patient subsample was analyzed by looking at the association between time-one to time-two when using a correlation between all domains grouped together, and also between each of the 9 patient domains separately. For complete details see Table 10. Test-Retest Reliability. When all domains were grouped together, a very high association between time-one and time-two was attained, with an ICC value of 0.905 ($p<0.0001$), supporting test-retest reliability of the English-language PelFIs questionnaire. Reliability of the document was further supported by 8 of the 9 domains having ICC values exceeding the ICC=0.70 critical value. Domain Urinary Incontinence fell slightly short of this benchmark, with ICC=0.692. The ICC values of the 8 significant domains ranged between ICC=0.774 ($p<0.0001$) for domain Constipation, and up to ICC=0.921 ($p<0.0001$) for domain Pelvic Organ Prolapse. The second hypothesis of this research study has been supported by the determination of test-retest reliability of the English-language PelFIs.

Internal Consistency

Internal consistency was determined by correlating items within domains. Pearson's Correlation was used to detect differences between domains, with the acceptable coefficient for group differences being 0.70. The details of these results are shown in Table 11. Significant correlation between domain Urinary Incontinence and domain Obstructive Micturition was determined with r=0.72324. Domain Constipation was found to be significantly correlated with domain Pelvic Pain with r=0.73703, and

finally domain Pelvic Pain and domain Sexual Dysfunction were highly correlated with r=0.87025. Additionally, there were four domain correlations that while not meeting the critical r-value, should be noted as approaching the necessary criteria. These connected domains were domain Micturition Pattern and domain Obstructed Micturition, with r=0.66910, domains Defecation Pattern and Constipation, with r=0.68081, domains Defecation Pattern and Fecal Incontinence with r=0.67937, and finally domains Constipation and Fecal Incontinence with r=0.66929.

Overall, the three bladder domains showed significant correlation between domains Micturition Pattern and Urinary Incontinence and approaching significance for comparison between domains Micturition Pattern and Obstructed Micturition. Surprisingly, the third combination of bladder domains, domains Urinary Incontinence and Micturition, was not as highly correlated with r=0.56714. The three bowel domains showed correlation, just falling short of the significant r-value for all three possible combinations, i.e. domains Constipation and Defecation Pattern, domains Constipation and Fecal Incontinence, and domains Defecation Pattern and Fecal Incontinence. Domain Constipation was also significantly correlated with domain Pelvic Floor Pain, as was the combination of domains Pelvic Pain and Sexual Dysfunction. Domain Pelvic Organ Prolapse showed no significant correlations with other domains, however, was most highly correlated with domain Pelvic Floor Pain (r=0.55850).

In addition to the inter-correlations, Cronbach's alpha was used to assess internal consistency of the scales. A high alpha value reflects that all items co-vary to the same degree, with alpha values of 0.70 or greater, considered significant. Cronbach's alpha was determined for each of the nine domains (see Table 12. Cronbach's Alpha for

Domains) and eight of the nine domains exceeded the significant value, with only domain Sexual Dysfunction falling short with alpha=0.580. For domain Pelvic Organ Prolapse, alpha=0.854 would increase to 0.865 with the removal of question 54, “Do you feel that mucous membrane or other tissue spontaneously comes out of your anus during running, or bowel motion?”. For domain Micturition Pattern, question 73 was removed before calculating Cronbach’s alpha. This was because the VAS question was a repeated question from domain Pelvic Organ Prolapse, and not relevant to domain Micturition Pattern. The remaining 16 items scored a significant alpha value of 0.734, which could be increased to 0.769, with the removal of question 63, “Can you put off urinating if you are sitting quietly?”. The VAS question 81 relating to domain Pelvic Organ Prolapse was again removed from domain Urinary Incontinence before determining Cronbach’s alpha to be 0.880. With the removal of question 78d, “Does the urine leakage occur with turning over in bed?”, the alpha value would increase to 0.883. Domain Obstructive Micturition can improve from alpha=0.734, to 0.740, with the removal of question 90, “Do you use a catheter?”. For domain Defecation Pattern, the alpha=0.704 would increase to 0.722 with the removal of question 95, “If you feel an urge to empty your bowels, when do you go to the toilet?”. Domain Fecal Incontinence can be increased from alpha=0.859 to alpha=0.866, following the removal of question 108, “Do you feel that feces are leaking?”. The alpha value of 0.733 may be increased to 0.746 by removing the VAS question 127, “Can you indicate below with a cross on a scale of 0 to 10 how you are experiencing your complaints with regard to bowel movement at this moment?” for domain Constipation. And finally, domain Pelvic Floor Pain can increase its alpha of 0.799 to 0.821 with the removal of the VAS question 136,

"Can you indicate below with a cross on a scale of 0 to 10 how you are experiencing the complaints with regard to the pain at this moment?". However, even with the removal of one of the six items within domain Sexual Dysfunction (question 137, "Do you have intercourse?"), the increased alpha of 0.598 would not reach significance. For the remaining domains, the removal of the suggested item would not only further increase the alpha value, but also assist in reducing the large number of items within this document.

Identifying Significant Items

The fourth objective aimed to identify the most useful and beneficial questions to gain information toward a minimum data set to create a shorter version of the English-language PelFIs. Nonparametric tests were used to analyze the patient responses against the control responses to each individual question within the document. For 'yes' and 'no' format questions, discreet-level data is collected and therefore Chi-Squared testing was used, with $p<0.05$ being significant. For questions collecting ordinal-level data, Wilcoxon Rank Sum Testing was used, with the same critical value for significance. If significant difference was noted between the two groups, then this item was deemed highly useful and beneficial to the data set. Those questions not showing significant difference between patients and control participants were considered relatively less informative and marked for possible removal in future PelFIs editions. The results are detailed in Table 13.

DISCUSSION

When comparing groups of individuals, it is important that these groups are essentially similar in all aspects, with the exception of any inclusion or exclusion criteria that would define the groups as distinct. The differences in health status noted in Table 1 and Figure 2, and the incongruity in involvement of medical disciplines (Table 1, Figure 3), medical conditions (Table 1, Figure 4), medications prescribed (Figure 6), and surgical procedures (Table 1) can be explained, at least partially if not substantially, by the definitions of the groups themselves. The inclusion criteria for the patient population stated that these participants must be seeking medical treatment for a pelvic floor related dysfunction. For this reason, it is expected that the categories listed above (i.e. health status, involvement of other medical disciplines, presence of other medical conditions, medications prescribed, and past surgical procedures), be significantly represented by the patient population. The connection between the pfm, respiratory illness and low back pain may also explain the overrepresentation of patients versus control participants within the 'back pain' and 'lung condition' categories. Additionally, as the control group exclusion criteria restricted females who had previously sought medical attention, or had or were currently, prescribed medications for pelvic floor related dysfunctions, it is logical to expect that the categories listed above would be underrepresented within the control population. The dramatic difference in oral contraceptive usage between the groups, with the control participants notably higher than the patients, may possibly be due to the vaginal drying effect of these medications. For patients experiencing pelvic

floor pain or sexual dysfunction, discontinuing the use of oral contraceptives, or avoiding usage, may be in attempt to normalize natural vaginal lubrication in hopes of decreasing pelvic pain and dysfunction.

Some differences between the activity levels of the two groups were noted in Table 1, as patients were shown to be somewhat less consistent with physical activity than the control participants. This may also be explained by the fact that a portion of the patient population suffered with painful or debilitating medical conditions and may be limited in mobility and activity. Additionally, those patients experiencing bladder or bowel control issues may resist exercise and excessive physical activity to avoid the embarrassment and frustration of soiling upon exertion.

While the overall number of pregnancies of both groups was comparable, it should be noted that the control group more than doubled the patient population in the category of 'never having been pregnant' and the patients doubled the control participants in the 'four or more pregnancies' category. These findings are directly relevant and must be distinguished as pregnancy (of greater than twenty weeks), which has been shown to greatly increase the prevalence of major pelvic floor dysfunction (34). With regard to birth history, Figure 1, showed surprisingly marked likeness between groups in mode of delivery, prevalence of severe and superficial tearing and use of forceps and vacuum extraction. These similarities were unexpected, as these categories have been linked with pelvic floor dysfunction in the literature.

The differences noted between the groups can be explained at least in part, if not substantially, by the definitions of the groups themselves. However, some of the

differences such as control participants being more highly representative for ‘never having been pregnant’, patients being more likely to have ‘4 or more pregnancies’, having had episiotomies, and displaying longer stages of pushing during vaginal delivery, highlight the need for further investigation into the relationship between these factors and pelvic floor dysfunction. It would be interesting to also investigate the increased concerns of irregular menstrual cycles and menopausal symptoms for the patients versus the control participants.

Items Related to Toileting Biomechanics

Within the English-language PelFIs, two items of interest relate to proper biomechanics when toileting. These questions are intended to detect participants that may benefit from education on proper toileting postures and habits. The first item was question 65, “How do you urinate?”, included within domain Micturition Pattern. Urinary posture was evaluated as participants were asked if they ‘sit, hover, or sit when at home and hover elsewhere’, during voiding. While the presence of hovering to eliminate urine is considered poor biomechanical voiding posture and may lead to future dysfunctional symptoms, detection of ‘hovering’ to void, in participants, was not considered a dysfunction within the bladder domains. The inclusion of this question was intended to direct the clinician to focus on further biomechanical toileting analysis and educate on proper toileting postures (when using the PelFIs as a diagnostic tool for clinical evaluation). The fact that more control participants (13 of 50) were found to hover over the toilet when voiding, compared to patients (9 of 50), may be explained by

the patient's necessity to change voiding postures, once a dysfunction is present, and patients may be forced to alter past behaviors and practices to attempt a more complete bladder emptying, by sitting to void. The second item used for detection of poor biomechanics when toileting, was question 124, "Do you have to push hard to pass the stool?". Patients were found to 'regularly or always' strain with defecation more frequently (3 of 50) than the control participants (1 of 50), however it is difficult to determine if these habits led to dysfunctions within the bowel domains or resulted because of symptoms with difficult bowel evacuation. Further research is necessary to determine whether the presence of these poor toileting habits contributed to pelvic floor dysfunction or if the symptoms of pelvic floor dysfunction led to poor biomechanics with urination and defecation.

Restructuring Likert Options

For a few items on the English-language PelFIs, choosing to rephrase questions may lead to increased usability of information gathered. Two of the Likert-format items on the questionnaire would benefit from restructuring the selection choices for participants. On numerous occasions during data collection, participants voiced concerns of confusion as their experience of symptoms fell equally within two separate options. Later, during the data analysis phase of this study, the structuring of the objective values within the choices produced difficulties that could be easily avoided by rewording the items.

One example of this would be question 58;

How often on average do you urinate at night?

a. never
b. 1-2 x per night
c. 3-4 x per night
d. more than 4 x per night

Patients (56%) and control participants (54%) displayed significant and virtually equal dysfunctions with waking to void 1 to 2 times per night. It would be interesting to further delineate this category into single voids versus a secondary waking to void per night, as clinically it is significantly more concerning to note two voids per night versus one void per night. This is because some single episodes of waking to void may be explainable and acceptable. For instance, if nocturia occurs when someone is twelve hours into sleep, it is understandable that the bladder may require emptying, whereas waking two hours into sleep would be more concerning, clinically.

This same issue of phrasing and structuring the selection options arose again in question 97;

How often on average per week do you have a bowel movement in the daytime?

a. 1 x per 2 weeks
b. 1 x per week
c. 3-4 x per week
d. 1-2 x per day
e. several times per day
f. other. Please indicate:_____

Participants reported difficultly answering this question as many vary in bowel schedules from week to week. Additionally, some selections made analysis difficult. For example, selection of ‘e. several times per day’ assumes that participants will select this

option if they experience greater than 2 movements per day as they would select option ‘d. 1-2 x per day’ if they most commonly experience 2 bowel movements per day. While the current wording was often difficult for participants to complete, the further concern arises when analyzing the responses. The criteria for acceptability, following the Rome guidelines of anywhere from, and including, 3 bowel movements per week up to 3 bowel movements per day, being a normal response. For those participants selecting ‘e. several times per day’, if they experience three movements per day it would fall into the acceptable schedule however, if this reflects more than three per day it would be considered dysfunctional. For this study, responses of ‘e. several times per day’ were considered within the acceptable range when analyzed, as it was impossible to determine whether the response reflected three, or more than three, movements per day.

Outcome of Present Study

The present study fulfilled its first objective and established construct validity by quantifying the differences in prevalence of pfm dysfunction between the patient population and the control population. Construct validity was supported with very significant findings ($p<0.0001$) of the discriminant analysis of the complete group of patients being compared to the complete group of control participants, and further supported by t-tests between individual domains all showing significant differences. Although the presence of pfm dysfunction within the control population was anticipated and shown to be prevalent, very significant differences between the two populations was achieved.

Content validity was attained from experts in the field analyzing and evaluating each of the nine separate domains, as well as the English-language PelFIs as a whole document. Furthermore, these experts provided invaluable suggestions on areas that may benefit from adjustment for future development. The domain Sexual Dysfunction and the section of Medical Intake questions, stand to gain valuable strength if adjusted in future PelFIs developments.

The second objective of this study was successfully achieved by determining test-retest reliability, as no significant differences were found between time-one and time-two of the questionnaire administrations. ICC for all domains combined was highly significant, with ICC=0.905, $p<0.0001$. Additionally, domains were each separately analyzed for association with the ICC exceeding the critical value of significance in 8 of the 9 domains. Domain Urinary Incontinence fell slightly short of significance as ICC=0.692.

Internal consistency was confirmed via Pearson's Correlation Coefficients between the domains, as well as determination of a significant Cronbach's alpha, for eight of the nine domains. For growth and development of the document, single items of each domain were isolated for consideration of future removal. In addition to increasing Cronbach's alpha for the corresponding domain, the removal of these items would assist in decreasing the overall length of the English-language PelFIs.

The third objective and of this research study was met by detecting the presence of co-occurrence of pfm disorders within patients that present for treatment of a single pfm dysfunction. The presence of co-occurrence was quantified and the

existence of pelvic floor symptoms in domains other than the domain the patient was diagnosed with dysfunction, determined. For example, patients presenting to the clinic with urinary incontinence displayed symptoms in subsequent bladder domains such as domain Micturition Pattern, but also patients commonly reported symptoms in bowel domains and pelvic pain domains as well. Every patient (100%) was shown to have symptoms in domains other than the domain for which they sought medical treatment. This supports the importance of complete and thorough medical investigation of all pelvic organs and assessment of the pfm, when patients present with concerns affecting a single pelvic organ.

The fourth and final objective of this research study was shown with the use of non-parametric tests, individually comparing the patient responses to those of the control participants, for each PelFIs item. For those questions where there was no difference in the responses given by the control participants and those given by the patients, it was concluded that the item did not distinguish between the two groups and therefore would be considered for removal for future development of a shorter-version PelFIs. In total, 108 items were analyzed with 30 items identified as unable to discern between the two groups and therefore considered for possible future removal from the PelFIs.

Limitations and Assumptions

It is an assumption that patients seeking medical attention for a single pfm dysfunction want additional pfm dysfunctions revealed so that earlier medical

intervention may be instituted. Since patients suffering with pfm dysfunction have been shown to delay seeking medical attention for many reasons including embarrassment to discuss symptoms of pfm dysfunction (2, 22, 24), perhaps patients seeking help and advice for a single pfm dysfunction are not receptive to advice and treatment in other areas of pfm dysfunction.

Because the results of this study are founded completely on the honesty and openness of participants to divulge personal information that may be embarrassing in nature, the study may be limited by the resistance of participants to discuss their symptoms in full due to the highly personal elements and sensitive nature to the questions. There is no way of detecting that full disclosure and accuracy has been maintained during data collection.

This study relies on the recollection of memory to determine answers to specific habits. Many of the questions related to behaviors that people often have not given much, if any, previous thought. As such it may be difficult to produce answers accurately reflecting their behaviors, such as number of voids per day, length of time delay between urinary urgency symptoms, etc.

The physiotherapists administering the questionnaires were advised not to deviate from the verbal reading of the items as they appeared on the document. We are assuming that participants had an understanding of medical terminology such as ‘perineal pressure’ and ‘mucous membrane’. It is possible that misunderstanding of terms may have affected the answers given.

As there was no possibility to ‘blind’ the physiotherapist from the population they were questioning, the therapists were reminded to ask questions with neutrality and

avoid encouraging control participants toward the answers reflecting ‘normal’ behavior. Even so, control participants may want to give ‘pleasing’, or the perceived ‘correct’ answers and there is no way to control for this.

Patients seeking help may differ in several variables such as severity of symptoms, cultural background, socio-economic and educational status, age, access to insurance coverage, and contact with specific physicians.

The overall length of the English-language PelFIs was also a limitation as several participants became frustrated with the amount of time it took to complete. The high number of items can lead to annoyance of participants and this was further influenced by the highly sensitive nature of the questions, leaving participants feeling uncomfortable and wanting to be finished with the questionnaire administration process.

Identification of the above-mentioned limitations of the English-language PelFIs, serves to enhance future development of this useful assessment tool. It is imperative that areas of weakness be clarified to produce the best results possible. Similarly, by seeking the advice of experts in the field, areas that may benefit from revision have been noted. Single items in each domain have been highlighted for removal in subsequent editions of the PelFIs to further increase alpha values thereby ensuring that all items co-vary to the same degree, as well as decrease the overall length of this document. These findings direct attention to areas of relative weakness within the document that may be addressed in future development to further strengthen an already valid and reliable tool for comprehensive assessment of the pfm.

Suggestions for Future Development of the PelFIs

Throughout this research study, numerous areas have been identified for consideration of elimination, when further developing the PelFIs tool in the future. Appendix VI details a complete summary of these suggestions. Experts asked to assess the content validity of the PelFIs as a whole, indicated a need for improvement in accuracy of the current questions and noted concern of omission of necessary questions. The following lists several areas for evaluation within each domain, in hopes of addressing and these concerns and strengthening the noted areas.

Within the Medical Intake portion of the questionnaire, experts commented on the need for improvement of omissions, accuracy and relevance of the questions in this section. They further noted the necessity for addressing the relevance of the questions within the domain Pelvic Organ Prolapse. For this domain, item 54 ("Do you feel that mucous membrane or other tissue spontaneously comes out of your anus during running, or bowel motion?"), was found to be a lower-value item and would increase Cronbach's alpha to 0.865 (from 0.854) if removed. Perhaps this was one of the items that the experts considered to be less relevant and its removal may further serve to improve both content validity, as well as internal consistency, within this domain.

For domain Micturition Pattern, item 63 ("Can you put off urinating if you are sitting quietly?"), was found to be a lower-value question and was also identified to increase Cronbach's alpha to 0.769 (from 0.734) if removed. Additionally, items 61a ("Do you notice more urgency in the cold?"), 61b ("Do you notice more urgency if a tap is running?"), 61c ("Do you notice more urgency if you are nervous?"), 63 ("Can you put off urinating if you are sitting quietly?"), 65 ("How do you urinate? a) sitting, b)

hovering, c) at home sitting, elsewhere hovering. "), and 66 ("How does the urine come? a) spontaneously, b) must wait, c) it varies, d) other.") were considered lower-value items and suggested for future removal from the document. Item 58 ("How often on average do you urinate at night? a) never, b) 1-2 times per night, c) 3-4 times per night, d) more than 4 times per night."), may benefit in data analysis by separating the 1 to 2 times per night selection to individual answers.

Domain Urinary Incontinence fell short of the critical ICC value of 0.70, with ICC=0.692. Question 78d ("Does urine leakage occur on turning over in bed?), was identified as a lower-value item and its removal would increase Cronbach's alpha to 0.883 (from 0.880). Items 78e ("Does urine leakage occur on getting out of bed?") and 78g ("Does urine leakage occur around menstruation?") were also identified for consideration of removal as they also were found not significant on Chi-square testing. It would be interesting to see if the ICC level reached the critical level following the removal of these items.

Domain Obstructive Micturition was found to contain 4 lower-value items, including question 90 ("Do you use a catheter?"), which was also identified for removal for a minor increase to Cronbach's alpha to 0.740 (from 0.734). The remaining 3 lower-value items were questions 84 ("Is urinating itself painful?"), 85 ("When you have finished urinating and stand up, does it still dribble?"), and 91 ("As a child, did you ever wet the bed?").

Within domain Defecation Pattern 5 lower-value questions were identified, including item 95 ("If you feel the urge to empty your bowels, when do you go to the

toilet? a) urgency, b) fixed time."), which was also found to increase Cronbach's alpha to 0.722 (from 0.704) upon its removal. A second low-value item was question 97 ("How often on average per week do you have a bowel movement in the daytime? a) 1 time per 2 weeks, b) 1 time per week, c) 3 to 4 times per week, d) 1 to 2 times per day, e) several times per day, f) other, please indicate:_____."), was also isolated as an item that would benefit from rephrasing as the selection of having bowel movements 'several times per day' lacked the objectivity necessary for data analysis. Questions 94 ("Do you feel an urge to empty your bowels?"), 96 ("Does something always come out when you go to the toilet for a bowel movement?"), and 102 ("Do you have bright red bleeding during the bowel movement?"), also failed to reach significant values on nonparametric testing and were therefore deemed relatively less valuable items to be considered for removal on future PelFIs editions.

For domain Fecal Incontinence, 7 lower-value questions were identified, including item 108 ("Do you feel that feces are leaking"), which would increase Cronbach's alpha to 0.866 (from 0.859) with its removal. The remaining 6 lower-value questions were items 107a ("Do you have bowel incontinence with coughing, sneezing, pushing, laughing, walking, or with sport?"), 107b ("Do you have bowel incontinence on getting up from a chair or climbing stairs?"), 107c ("Do you have bowel incontinence on bending or lifting?"), 107d ("Do you have bowel incontinence on turning over in bed?"), 107e ("Do you have bowel incontinence on getting out of bed?"), and 118 ("Do you deliberately eat certain food to make the stool thicker or thinner?").

Within domain Constipation, VAS item 127 ("Can you indicate below with a cross on a scale of 0 to 10 how you are experiencing your complaints with regard to

bowel movement at this moment?"), was identified for removal to increase Cronbach's alpha to 0.746 (from 0.733). However, it should be noted that this item did reach significant values on Wilcoxon Rank Sums Testing and was therefore deemed a high-value question and therefore should not be considered for removal for a minor gain in alpha value.

Suggestions for improvement of domain Pelvic Floor Pain included the removal of the VAS item 136 ("Can you indicate below with a cross on a scale of 0 1o 10 how you are experiencing the complaints with regard to the pain at this moment?"), for an increased Cronbach's alpha to 0.821 (from 0.799). The removal of 3 low-value questions, items 128 ("Do you have pain around the anus after a bowel movement?"), 132 ("Do you ever have pain in the area around the tailbone?"), and 134a ("Do you have pain on penetration during intercourse?").

Experts in the field of pelvic pain, bladder, bowel and sexual dysfunction, illuminated the need for revamping of the domain Sexual Dysfunction as they noted omission of necessary questions, as well as critiquing the relevance of some of the items included. Perhaps the relevance rating of the domain will increase by the removal of item 137 ("Do you have intercourse?"), as well as benefiting from the increase in Cronbach's alpha to 0.598 (from 0.580). This item elimination alone will not achieve a significant value for internal consistency of the domain; however, the alpha will be further affected, hopefully positively, by the removal of the low-value question, 138 ("Are the complaints mentioned earlier of influence during intercourse?").

Finally, as research continues to investigate and uncover contributions of the pfm, this research tool can evolve to accommodate for these findings. While the pfm has been shown to play a significant role in core stabilization and postural support as well as assist diaphragmatic function during respiration, neither the Dutch-language PelFIs nor this English-language PelFIs assess these functions at this time. Further research in these areas is necessary before this tool would be able to encapsulate these functions. This may be an interesting area for further research and development of this tool.

CONCLUSIONS

Numerous assessment tools exist for the detection of dysfunction within specific pelvic organs, however, none elicit information for all possible pfm dysfunctions. The Dutch-language PelFIs was the first document to accomplish this comprehensively. The present study has shown the English-language PelFIs to be a valid and reliable tool for detecting and objectively measuring the complete extent of pfm dysfunctions. As this promising research tool has been previously shown as both valid and reliable in the Dutch-language, the PelFIs administered questionnaire may now be accessible to clinicians on a worldwide scale, to be used as a research tool as well as a clinical outcome measure.

Clinical Relevance

Pelvic floor dysfunction affects women on a global scale and in staggering numbers. The common element physically connecting the bladder, uterus and bowel is the pfm. The pfm has been found to be dysfunctional in 77.2% of patients presenting for urinary, gastrointestinal and sexual symptoms (35).

As these dysfunctions are often embarrassing in nature and society reinforces the fallacies that these symptoms are simply a normal and acceptable fact of life for women, most learn to live with their symptoms and few are aware that help is available. For those who do seek help, many will not realize the realm of pfm dysfunction and

therefore will not discuss all symptoms they are experiencing, not realizing that these other symptoms may be relevant to the issues bringing them to the clinic.

It has been suggested that when assessing a female presenting with pelvic floor dysfunction, it is necessary to ask questions on all areas of pelvic floor dysfunction since co-occurrence is common and therefore, to ensure proper health care, all must be investigated. When pelvic floor dysfunction is left undiagnosed, individuals can suffer from disorders in other pelvic organs, leading to negative effects on quality of life and social and work interaction (5).

It is this all-encompassing evaluation of pfm function that makes the English-language PelFIs a unique contributor to furthering the development of patient care and research. The field of pelvic floor physiotherapy will benefit by offering this uniform and comprehensive measurement tool for the detection of all possible pfm dysfunction during history-taking and thus translate to patient treatment with the highest quality of care. As well, medical practitioners from all disciplines will benefit from this document as it provides all questions necessary for guidance through a fully encompassing pelvic floor assessment addressing dysfunctions that may be outside the scope of a specific practitioners specialty.

In conclusion, this administered questionnaire was shown to be valid and reliable in the English language. Furthermore, information was gathered for direction to segments of the document that may benefit from enhancement to further strengthen the PelFIs. As well, identification of the highest information-eliciting questions was determined, thus allowing for future expansion to a shorter-version assessment device. Development of the English-language PelFIs is important for medical practitioners

working in the field of pelvic floor dysfunction, not only as a diagnostic and assessment tool, but also as an outcome measurement for treatment and research.

FIGURES

Figure 1. Birth History of Participants

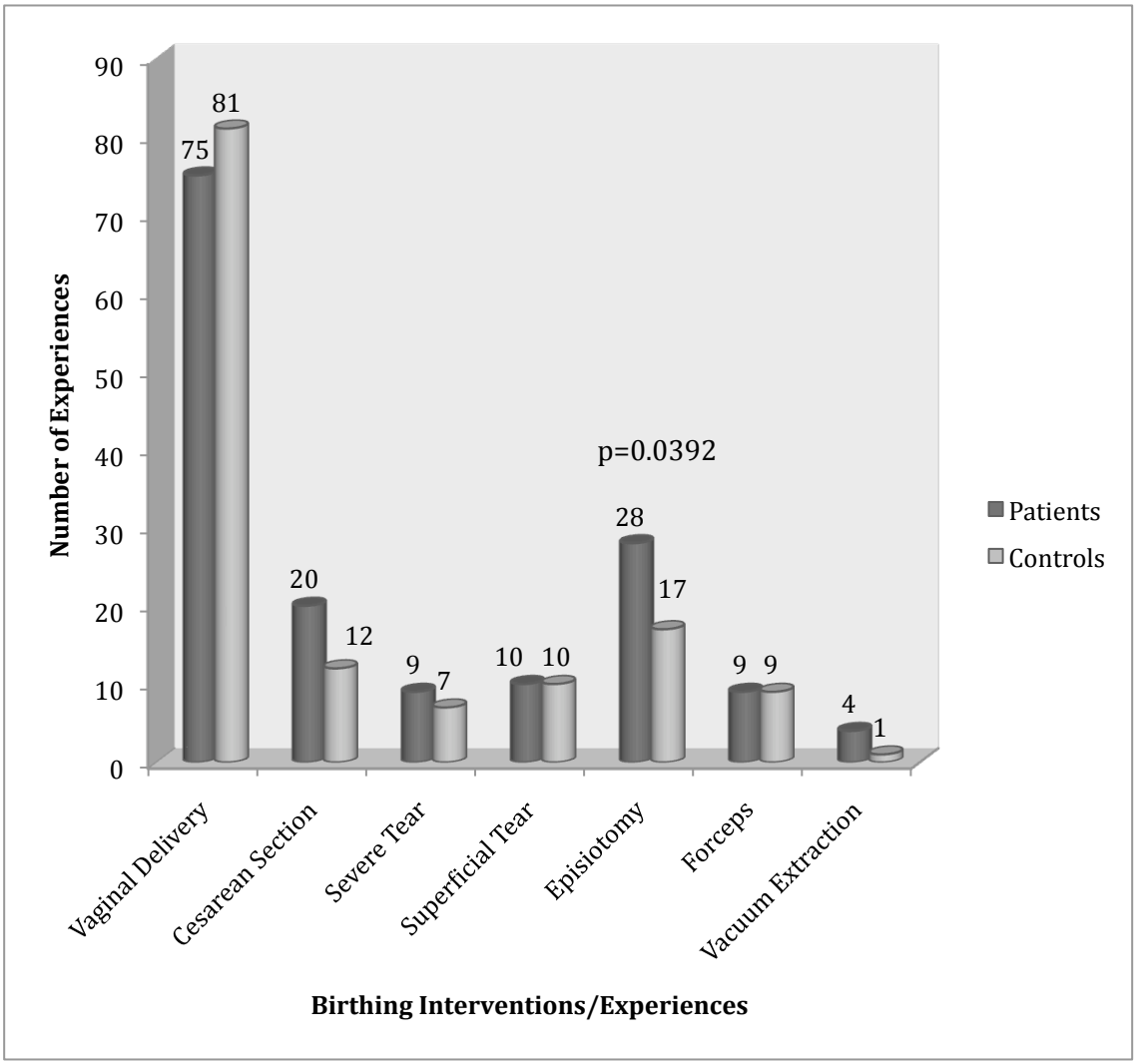

Figure 2. Health Status of Participants

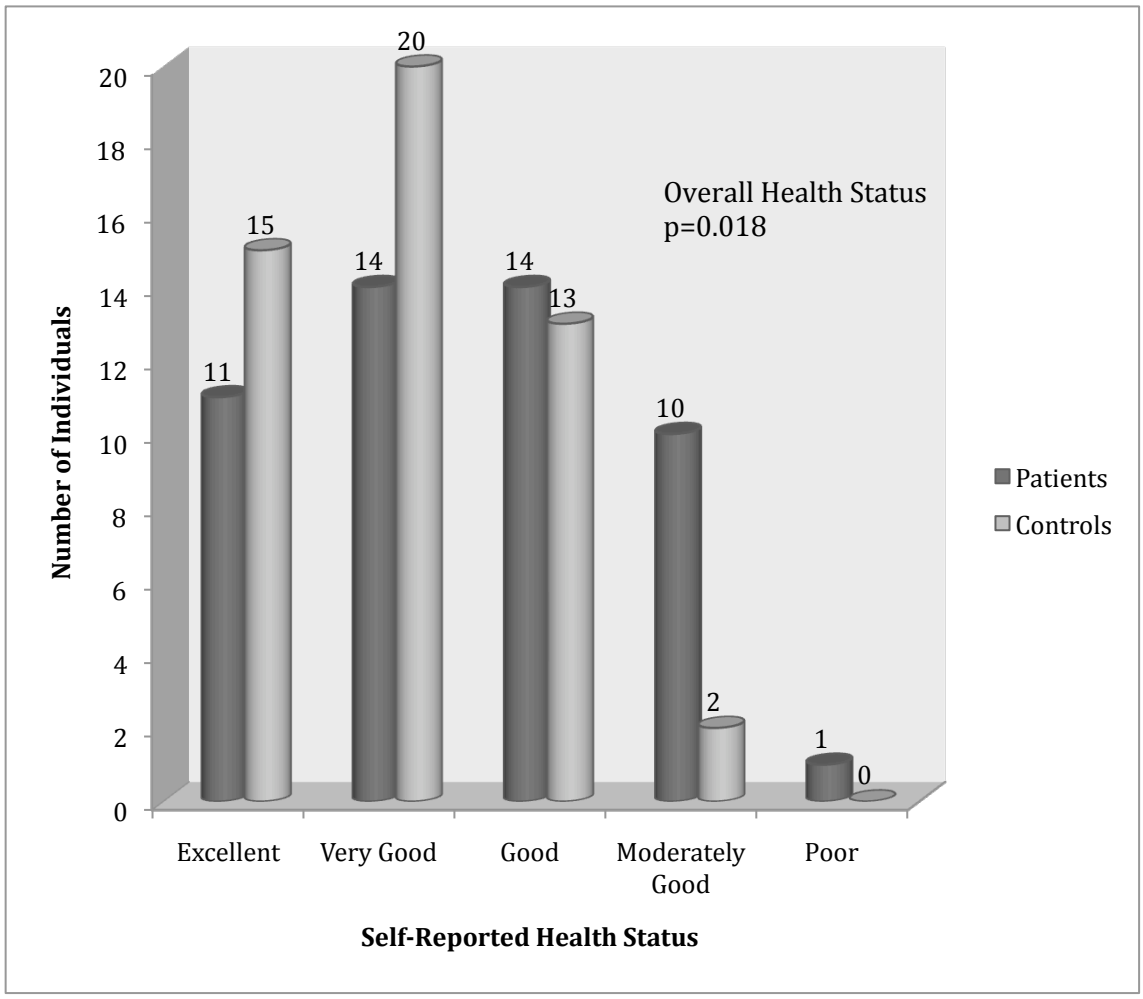

Figure 3. Medical Care of Participants

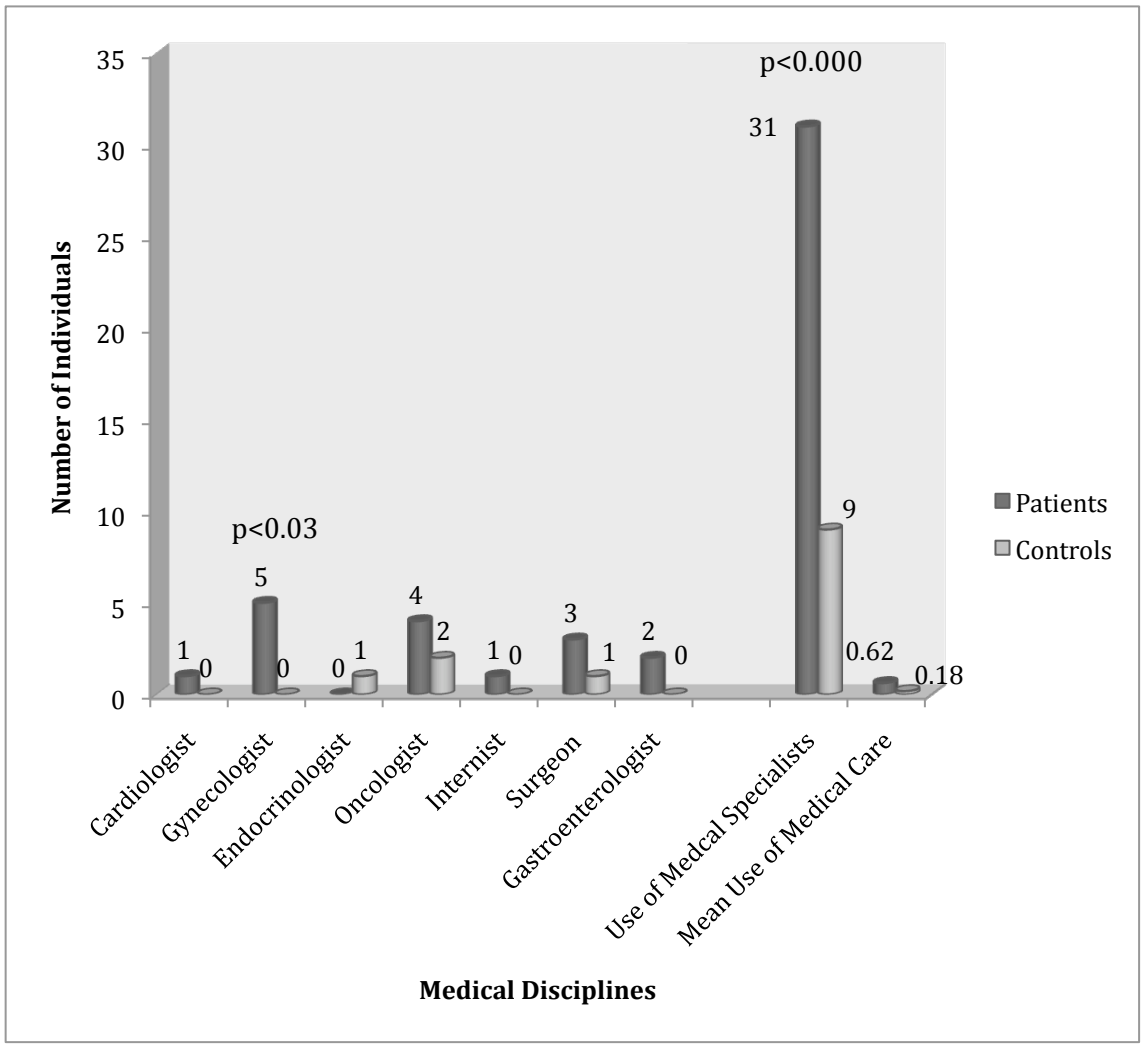

Figure 4. Medical Conditions of Participants

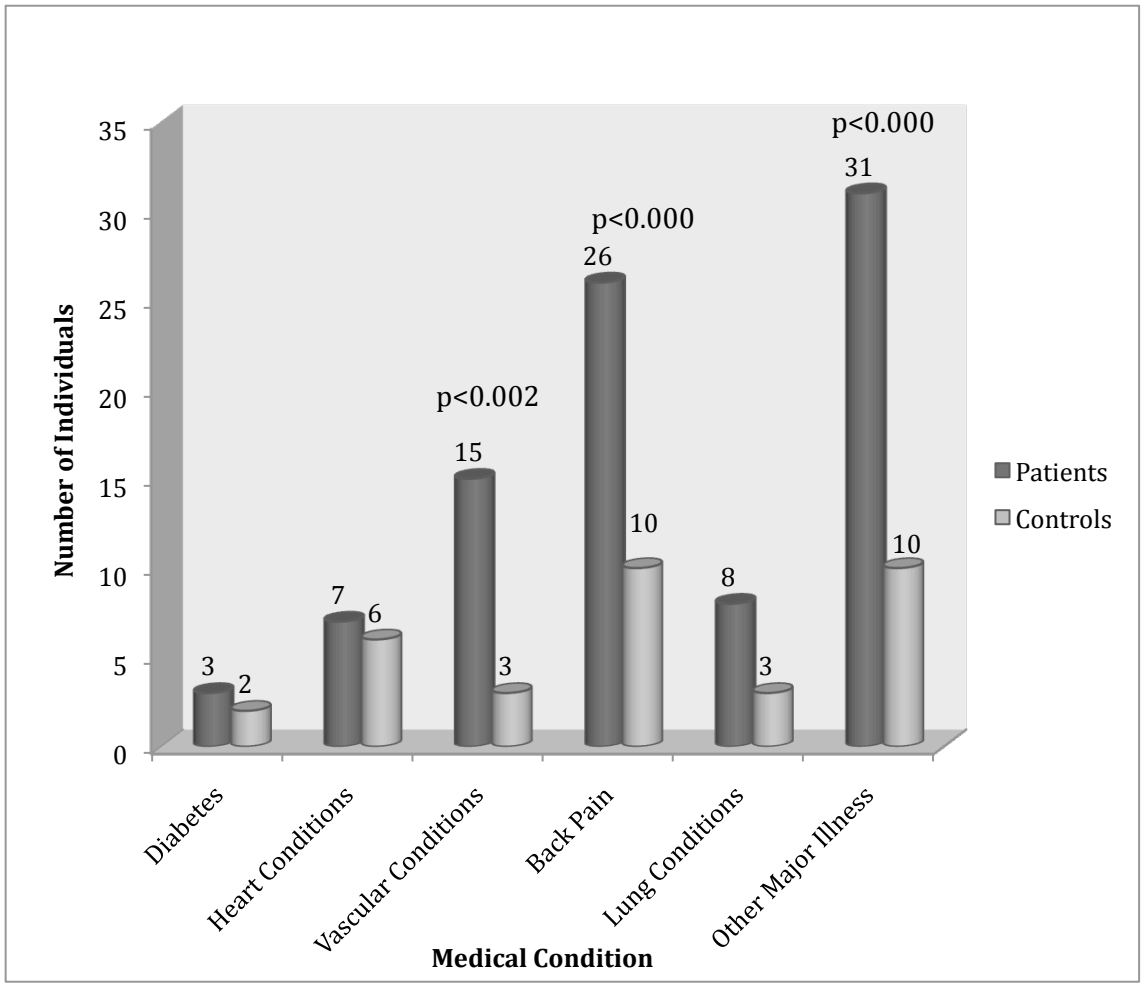

Figure 5. Menstruation Status of Participants

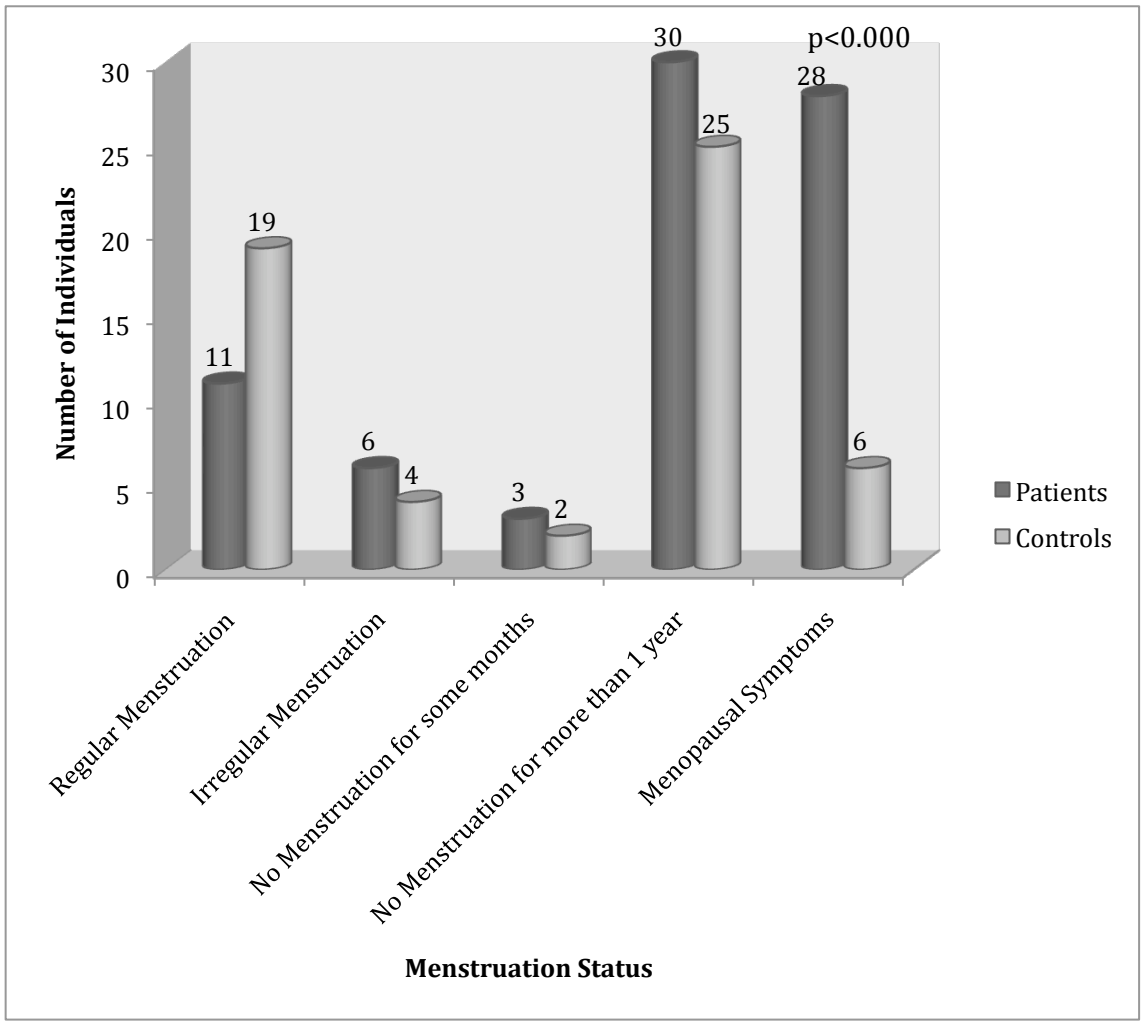

Figure 6. Medications of Participants

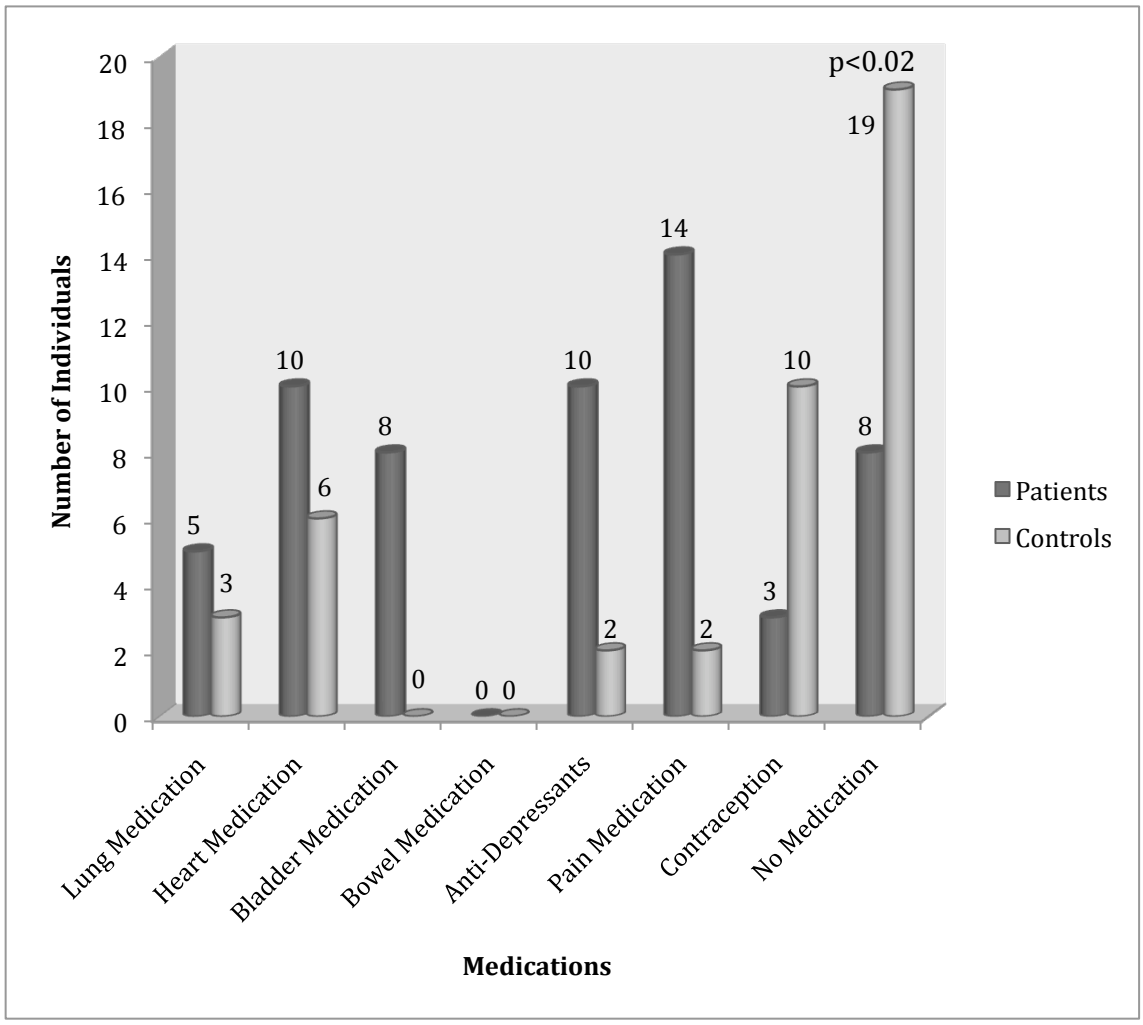

Figure 7. Length of Pushing During Labour

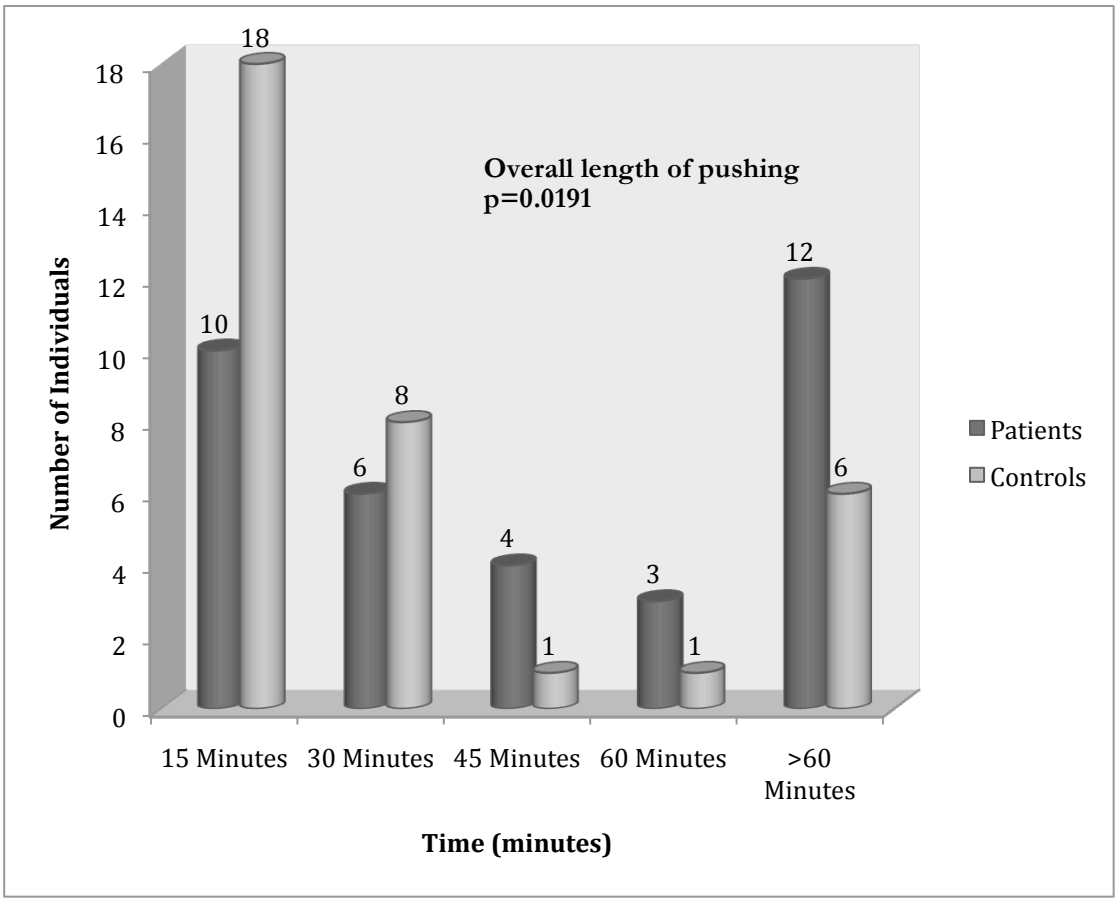

Figure 8. Total Number of Dysfunctions Detected within Individual Domains

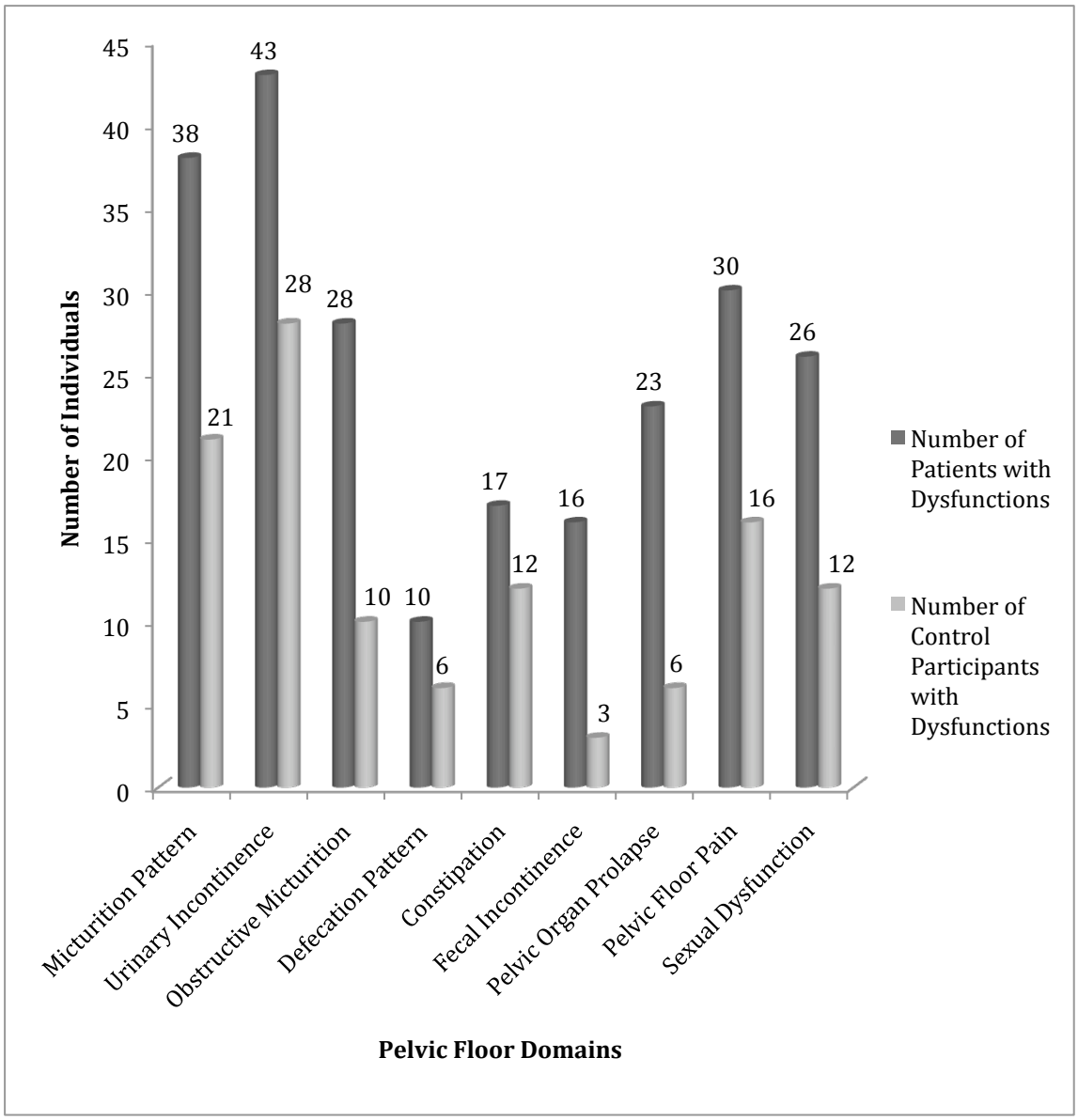

FIGURE LEGENDS

Figure 1. Birth History of Participants

This figure summarizes the similarity in overall birthing history between the patient population (n=50) versus the control population (n=50) studied. Birthing intervention and experience categories are detailed along the x-axis with the number of experiences filling each birth history category along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. The two groups showed significant differences within the 'episiotomy' category (28 patients, 17 control participants, p=0.0392), and less notable differences within the categories 'cesarean section' (20 patients, 12 control participants) and 'vacuum extraction' (4 patients, 1 control participant). The categories 'vaginal delivery' (75 patients, 81 control participants), 'severe tearing' (9 patients, 7 control participants), 'superficial tearing' (10 patients, 10 control participants), and 'forceps' (9 patients, 9 control participants), were all similarly, or identically, matched. The overall birth history was found comparable between the two groups.

Figure 2. Health Status of Participants

This figure summarizes the similarity in health status between the overall patient population (n=50) versus the control population (n=50) studied. Categories of self-reported health status are listed along the x-axis with the number of individuals filling each health status category along the y-axis. The patient population is represented in

dark grey with the control participants appearing in light grey for ease of visual comparison. Participants were asked to give a rating reflecting their perception of their overall health. While some of the health categories showed differences, for example health status category 'moderately good' (10 patients, 2 control participants), the remaining categories 'excellent' (11 patients, 15 control participants), 'very good' (14 patients, 20 control participants), 'good' (14 patients, 13 control participants), and 'poor' (1 patient, 0 control participants), were very similar in representation of the two groups. Overall, we have similarity between the patient population and the control population.

Figure 3. Medical Care of Participants

This figure summarizes the comparison in medical care between the patient population (n=50) versus the control population (n=50) studied. Categories of medical disciplines are listed along the x-axis with the number of individuals filling each medical discipline category along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. The two groups showed significant differences within the 'gynecologist' (5 patients, 0 control participants, p=0.0218), and 'use of medical specialists' (31 patients, 9 control participants, p=0.0004), categories and less notable differences within the categories 'oncologist' (4 patients, 2 control participants), 'surgeon' (3 patients, 1 control participants) and 'gastroenterologist' (2 patients, 0 control participants). The categories 'cardiologist' (1 patients, 0 control participants), 'endocrinologist' (0 patients, 1 control participant), and 'internist' (1 patient, 0 control participants), were all similarly

matched. The overall use of medical care was found higher for the patient group (mean=0.62) compared to the control group (mean=0.18).

Figure 4. Medical Conditions of Participants

This figure summarizes the comparison in medical conditions between the overall patient population (n=50) versus the control population (n=50) studied. Categories of medical conditions are listed along the x-axis with the number of individuals filling each medical condition category along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. Patients were overly represented in every medical condition category when compared to the control participants. The two groups showed significant differences within the 'vascular condition' (15 patients, 3 control participants, $p=0.0018$), 'back pain' (26 patients, 10 control participants, $p=0.0009$), and 'other major illness' (31 patients, 10 control participants, $p<0.0001$) categories and less notable differences within the category 'lung condition' (8 patients, 3 control participants). The categories 'diabetes' (3 patients, 2 control participants) and 'heart condition' (7 patients, 6 control participants), were similarly matched. The overall comparison of medical conditions was found notably higher for the patient group than the control group.

Figure 5. Menstruation Status of Participants

This figure summarizes the comparison of menstruation status between the patient population (n=50) versus the control population (n=50) studied. Categories of menstruation status are listed along the x-axis with the number of individuals filling each menstruation category along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. The two groups showed significant differences within the 'menopausal symptoms' (28 patients, 6 control participants, $p<0.0001$) category and less notable difference within the category 'regular menstruation' (11 patients, 19 control participants). The categories 'irregular menstruation' (6 patients, 4 control participants), 'no menstruation for some months' (3 patients, 2 control participants), and 'no menstruation for more than 1 year'(30 patients, 25 control participants), were all similarly matched. Overall, the menstruation status between the groups was similar regarding those still menstruating versus those experiencing menopause, however, the notable finding is that the patient population reports over 4.5 times more concerns with menopausal symptoms compared with the control group.

Figure 6. Medications of Participants

This figure summarizes the comparison of pharmaceutical usage between the patient population (n=50) versus the control population (n=50) studied. Medication categories are listed along the x-axis with the number of individuals filling each medication category along the y-axis. The patient population is represented in dark grey

with the control participants appearing in light grey for ease of visual comparison. The two groups showed notable differences within the use of 'bladder medication' (8 patients, 0 control participants), 'anti-depressants' (10 patients, 2 control participants), 'pain medication' (14 patients, 2 control participants), 'contraception' (3 patients, 10 control participants), 'other medication' (29 patients, 11 control individuals) and 'no medication' (8 patients, 19 control participants) categories and less notable differences within the categories 'lung medication' (5 patients, 3 control participants) and 'heart medication' (10 patients, 6 control participants). The category 'bowel medication' (0 patients, 0 control participants) was identically matched. The overall medication consumption was found significantly higher for the patient population when compared to the control population ($p=0.0155$) with the exception of the category 'contraception' which was notably higher for the control population. Also noteworthy is that over twice as many control participants reported no medication use than the patients. The report of no consumption of bowel medications within the patient group was surprising.

Figure 7. Length of Pushing During Labour

This figure summarizes the length of pushing during birthing between the patient population ($n=50$) versus the control population ($n=50$) studied. The categories of time in 15-minute groupings are listed along the x-axis with the number of individuals filling each category along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. The two groups showed notable differences within the '15 minutes' category with 18 control participants filling this category compared to only 10 patients reporting this short period

of pushing during labour. As well, the longest period of pushing during labour, the 'greater than 60 minutes' category, was represented with 12 patients compared to only 6 control participants. Less notable differences were found within the categories '30 minutes', '45 minutes' and '60 minutes'. Overall, a dramatic difference was noted on both ends of the spectrum with 26 of the control participants compared to 10 patients having pushed 30 minutes or less, while only 8 control participants, compared to 19 patients, reported pushing for 45 minutes or more, during their labours. The Mantel-Haenszel Chi-squared p-value of 0.0191 supports a significant difference in the length of time spent pushing during vaginal labour for two groups, with the patient population pushing significantly longer than the control population.

Figure 8. Total Number of Dysfunctions Detected within Individual Domains

This figure summarizes the total number of individuals (n=50 patients plus n=50 control participants) who experience dysfunction within the respective domains. The nine pelvic floor domains are listed along the x-axis with the number of individuals filling each domain along the y-axis. The patient population is represented in dark grey with the control participants appearing in light grey for ease of visual comparison. For the three bladder domains, 38 patients compared to 21 control participants noted dysfunction in domain Micturition Pattern, 43 patients and 28 control participants experienced dysfunction in domain Urinary Incontinence, and domain Obstructive Micturition was found dysfunctional for 28 patients and 10 control participants. For the three bowel domains, 10 patients and 6 control participants noted dysfunction in domain

Defecation Pattern, 16 patients versus 3 control participants suffered with dysfunction in domain Fecal Incontinence, and domain Constipation was found dysfunctional for 17 patients and 12 control participants. Finally, for the remaining three domains, 23 patients and 6 control participants reported dysfunction for domain Pelvic Organ Prolapse, 30 patients and 16 control participants suffered with dysfunction in domain Pelvic Floor Pain, and domain Sexual Dysfunction was evident for symptoms in 26 patients and 12 control participants.

TABLES

Table 1. Patient Versus Control Group Comparisons

Demographics

Characteristics	Data Level	Test Used	Results (Control Group/Patients)	p-value	Significance (P<0.05)
Age of Participants (years)	Continuous	Independent T-Test (Pooled)	48.78 ± 16.524 52.86 ±13.32	P=0.1772	No Significance
Overall Work Status	Categorical	Chi-Squared	62% full/part-time 14% housewife 24% retired 46% full/part-time 12% housewife 4% student 6% disability 32% retired	P=0.2849	No Significance
Sexual Partner Status	Categorical	Chi-Squared	96% have partner (male) 86% have partner (male)	P=0.0806	No Significance

Lifestyle

Characteristics	Data Level	Test Used	Results (Control Group/Patients)	p-value	Significance (P<0.05)
Current Smoking Status	Categorical	Chi-Squared	14% Smoke 14% Smoke	P=1.0000	No Significance
Past Smoking Status	Categorical	Chi-Squared	26% did smoke 36% did smoke	P=0.2615	No Significance
Alcohol Consumption (glasses/day)	Continuous	Independent T-Test (Pooled)	1.87 ± 2.26 1.51 ± 2.09	P=0.1384	No Significance
Caffeinated Coffee/Tea Consumption (cups/day)	Continuous	Independent T-Test (Satterthwaite)	2.23 ± 1.58 1.88 ±2.30	P=0.3703	No Significance
Caffeinated Soda Consumption	Continuous	Independent T-Test (Satterthwaite)	0.11 ±0.34 0.385 ±1.03	P=0.0772	No Significance
Activity Level (30-minute interval)	Ordinal	Mantel-Haenszel Chi-Squared	Never 2% Irregularly 14% 1x/week 4% 2-4x/week 42% Daily 38% Never 8% Irregularly 26% 1x/week 2% 2-4x/week 34% Daily 30%	P=0.4442	No Significance

Dietary Factors

Characteristics	Data Level	Test Used	Results (Control Group/Patients)	p-value	Significance (P<0.05)
Regular Eating Habits	Categorical	Chi-Squared	96% eat regularly 94% eat regularly	P=0.6464	No Significance
Fiber Intake in Diet	Categorical	Chi-Squared	90% good fiber intake 88% good fiber intake	P=0.7493	No Significance
Fluid Intake Levels (cups/day)	Ordinal	Mantel-Haenszel Chi-Squared	46% 4-6 36% 6-8 18% >8 6% <4 32% 4-6 36% 6-8 26% >8	P=0.5455	No Significance

Overall Health

Characteristics	Data Level	Test Used	Results (Control Group/Patients)	p-value	Significance (p<0.05)
Overall Health Status	Ordinal	Mantel-Haenszel Chi-Squared	70% excellent to very good 30% good to moderately good 50% excellent to very good 48% good to moderately good 2% poor	P=0.0181	Significant
Height (feet)	Continuous	Independent T-Test (Pooled)	5.41 ± 0.23 5.35 ± 0.21	P=0.1745	No Significance
Weight (pounds)	Continuous	Independent T-Test (Satterthwaite)	146.98 ± 21.66 153.94 ± 30.84	P=0.1950	No Significance
Body Mass Index	Continuous	Independent T-Test (Pooled)	24.67 ± 4.33 26.30 ± 5.13	P=0.888	No Significance
Under Care of Medical Specialist	Categorical	Chi-Squared	18% 52%	P=0.0004	Highly Significant
Care of Cardiologist	Categorical	Chi-Squared	0% 2%	P=0.3149	No Significance
Care of Gynecologist	Categorical	Chi-Squared	0% 10%	P=0.0218	Significant
Care of Endocrinol.	Categorical	Chi-Squared	2% 2%	P=1.0000	No Significance
Care of Oncologist	Categorical	Chi-Squared	4% 8%	P=0.3997	No Significance
Care of Internist	Categorical	Chi-Squared	0% 2%	P=0.3149	No Significance

Care of Surgeon	Categorical	Chi-Squared	2% 6%	P=0.3074	No Significance
Care of Gastroent.	Categorical	Chi-Squared	0% 4%	P=0.1531	No Significance
Care of Other Health Specialist	Categorical	Chi-Squared	12% 28%	P=0.2202	No Significance
Diagnosis of Diabetes	Categorical	Chi-Squared	4% 6%	P=0.6464	No Significance
Heart Condition	Categorical	Chi-Squared	12% 14%	P=0.7662	No Significance
Vascular Condition	Categorical	Chi-Squared	12% 30%	P=0.0018	Significant
Presence of Back Pain	Categorical	Chi-Squared	20% 52%	P=0.0009	Highly Significant
Lung Condition	Categorical	Chi-Squared	6% 14%	P=0.1824	No Significance
Presence of Other Major Illness	Categorical	Chi-Squared	20% 62%	P<0.0001	Highly Significant
Surgical Procedures	Categorical	Chi-Squared	Urologic 0 General 26 Gynecologic 19 Orthopedic 6 Thoracic 3 Urologic 5 General 36 Gynecologic 30 Orthopedic 9 Thoracic 2	P=0.5357	No Significance

Gynecologic & Obstetrical History

Characteristics	Data Level	Test Used	Results (Control Group/Patients)	p-value	Significance (P<0.05)
Number of Pregnancies	Ordinal	Mantel-Haenszel Chi-Squared	0 24% 1 2% 2 30% 3 32% 4+ 12%	P=0.3958	No Significance
			0 10% 1 12% 2 40% 3 12% 4+ 24%		
Birth Weights of Babies (pounds)	Continuous	Independent T-Test (Pooled)	8.09 ± 1.08	P=0.2786	No Significance
			7.81 ± 1.22		
Vaginal Birth	Ordinal	Mantel-Haenszel Chi-Squared	81	P=0.1566	No Significance
			75		
Cesarean Section	Ordinal	Mantel-Haenszel Chi-Squared	12	P=0.2597	No Significance
			20		
Pushing during labour (minutes)	Ordinal	Mantel-Haenszel Chi-Squared	15 36% 30 16% 45 2% 60 2% >60 12%	P=0.0191	Significance
			15 20% 30 12% 45 8% 60 6% >60 24%		
Use of vacuum extraction, forceps and induction	Categorical	Chi-Squared	9 forceps 1 vacuum	P=0.3657	No Significance
			9 forceps 4 vacuum		
Use of Episiotomy	Categorical	Chi-Squared	17	P=0.0392	Significant
			28		

Tearing of Perineum	**Ordinal**	**Mantel-Haenszel Chi-Squared**	**10 superficial 7 severe** **10 superficial 9 severe**	**P=0.7552**	**No Significance**
Menstruation Status	**Ordinal**	**Mantel-Haenszel Chi-Squared**	**46% menstruate 54% menopause** **34% menstruate 66% menopause**	**P=0.1620**	**No Significance**
Menopausal Symptoms	**Categorical**	**Chi-Squared**	**12%** **56%**	**P=<.0001**	**Highly Significant**

Table 2. Symptoms in Bladder Domains

Domain	Presence/Severity of symptoms)	Patients	Control participants
Micturition Pattern (daytime urinary frequency)	Too Low (2-4 voids/day)	5	7
	Too high (10+ voids/day)	1	9
Micturition Pattern (nocturnal urinary frequency)	1-2 voids/night	28	27
	3-4 voids/night	8	2
	>4 voids/night	1	0
Micturition Pattern (Bladder Urgency)	Constant	1	0
	<2 hours	25	10
	>4 hours	3	5
Urinary Incontinence		43	28
Obstructive Micturition (incomplete bladder emptying)	Bladder does not feel empty after voiding	21	8
Obstructive Micturition	Dribble upon standing up from voiding	17	14

Table 3. Poor Toileting Biomechanics

		Patients	Control participants
Hovering over Toilet During voiding (when not at home)		9	13
Straining with Bowel Movements	Seldom-Sometimes	37	33
	Regularly-Always	3	1

Table 4. Symptoms in Bowel Domains

Domain	Presence/Severity of Symptoms	Patients	Control participants
Defecation Pattern	1 Bowel Movement per week	1	1
	> 2 Bowel Movement per day	6	4
	Other	3	1
Fecal Incontinence		16	3
Constipation	'Never –Seldom' experience full bowel evacuation	6	3
	'Sometimes' experience full bowel evacuation	11	9

Table 5. Symptoms of Pelvic Organ Prolapse, Pelvic Floor Pain and Sexual Dysfunction

Domain	Presence/Severity of Symptoms	Patients	Control participants
Pelvic Organ Prolapse	Seldom-Sometimes	14	4
	Regularly-Always	5	0
Pelvic Floor Pain	Anal Cramping	13	3
	Perineal Pain	12	3
	Coccyx (tailbone) Pain	17	10
	Ischial Tuberosity (sit bones) Pain	16	8
Sexual Dysfunction	Pain with Intercourse	26	12
	Penetration Pain with Intercourse	18	10
	Deep Pain with Intercourse	24	6

Table 6. Number of Domains Patients Experienced Dysfunction

Number of Domains With Symptoms	Number of Patients
1	0
2	6
3	9
4	10
5	8
6	9
7	7
8	0
9	1

Table 7. PFM Dysfunctions Detected in Control participants

Number of Domains with Symptoms	Number of Control Participants
0	3
1	10
2	11
3	15
4	8
5	3

Table 8. Construct Validity: Domain Comparisons

Domain	Patients (mean ± sd)	Control Participants (mean ± sd)	Construct Validity Independent T-Tests
Micturition Pattern	17.37 ± 6.0658	11.55 ± 3.9217	T=5.70, p<0.0001
Urinary Incontinence	12.09 ± 5.7381	4.41 ± 4.3456	T=7.54, p<0.0001
Obstructive Micturition	14.36 ± 7.9662	3.98 ± 4.8676	T=7.86, p<0.0001
Defecation Pattern	4.58 ± 5.7146	2.06 ± 2.0841	T=2.93, p=0.0048
Constipation	9.33 ± 6.5236	4.63 ± 3.554	T=4.47, p<0.0001
Fecal Incontinence	14.19 ± 13.95	4.41 ± 4.1462	T=4.75, p<0.0001
Pelvic Organ Prolapse	4.59 ± 6.3965	0.56 ± 1.5207	T=4.33, p<0.0001
Pelvic Floor Pain	10.23 ± 8.9375	2.88 ± 3.9507	T=5.32, p<0.0001
Sexual Dysfunction	6.4 ± 5.6116	1.43 ± 2.3947	T=5.76, p<0.0001

Table 9. Content Validity Evaluation

	Relevance of Questions	Accuracy of Questions	Omissions of Questions	Section Rated Overall	Mean
Medical Intake Questions	2.875	2.500	2.375	2.625	2.594
Domain Pelvic Organ Prolapse	2.667	3.167	3.167	3.000	3.000
Domain Micturition Pattern	3.571	3.571	3.429	3.143	3.428
Domain Urinary Incontinence	3.714	3.857	3.286	3.571	3.607
Domain Obstructive Micturition	3.143	3.429	3.857	3.571	3.500
Domain Defecation Pattern	3.625	4.000	3.375	3.500	3.625
Domain Fecal Incontinence	3.750	3.750	3.875	3.750	3.781
Domain Constipation	3.625	4.000	3.625	3.625	3.719
Domain Pelvic Floor Pain	3.250	3.500	3.000	3.375	3.281
Domain Sexual Dysfunction	2.857	3.000	2.571	2.571	2.750
PelFIs (as a whole)	3.125	2.625	2.625	2.625	2.750
Mean	3.291	3.400	3.199	3.214	3.276

Table 10: Test-Retest Reliability

Comparison	Intraclass Correlation Coefficient (ICC)	P Value
PelFIs (all domains)	ICC=0.905	P=0.0001
Domain Micturition Pattern	ICC=0.826	P=0.0001
Domain Urinary Incontinence	ICC=0.692	Not Significant
Domain Obstructive Micturition	ICC=0.878	P=0.0001
Domain Defecation Pattern	ICC=0.868	P=0.0001
Domain Constipation	ICC=0.774	P=0.0001
Domain Fecal Incontinence	ICC=0.929	P=0.0001
Domain Pelvic Organ Prolapse	ICC=0.921	P=0.0001
Domain Pelvic Floor Pain	ICC=0.865	P=0.0001
Domain Sexual Dysfunction	ICC=0.820	P=0.0001

Table 11. Pearson Correlation Coefficients

Pearson Correlation Coefficients, N = 100 Prob > |r| under H0: Rho=0									
	domain POP	domain Mict	domain UI	domain ObMict	domain Defectn	domain FI	domain Constip	domain PF Pain	domain Sex Dysf
domain POP	1.00000	0.44611 <.0001	0.37934 <.0001	0.44589 <.0001	0.29454 0.0029	0.37078 0.0001	0.38320 <.0001	0.55850 <.0001	0.43862 <.0001
domain Mict		1.00000	0.56714 <.0001	0.66910 <.0001	0.34676 0.0004	0.41173 <.0001	0.46256 <.0001	0.48587 <.0001	0.54054 <.0001
domain UI			1.00000	0.72324 <.0001	0.15890 0.1143	0.37874 0.0001	0.22233 0.0262	0.25907 0.0092	0.32278 0.0011
domain ObMict				1.00000	0.18973 0.0587	0.35580 0.0003	0.31726 0.0013	0.39986 <.0001	0.42627 <.0001
domain Defectn					1.00000	0.67937 <.0001	0.68081 <.0001	0.59520 <.0001	0.45587 <.0001
domain FI						1.00000	0.66929 <.0001	0.62672 <.0001	0.47225 <.0001
Domain Constip							1.00000	0.73703 <.0001	0.62057 <.0001
domain PF Pain								1.00000	0.87025 <.0001
domain Sex Dysf									1.00000

Table 12. Cronbach's Alpha for Domains

	Number of Items	Alpha Value	Possible Alpha if Single Item Removed
Domain Pelvic Organ Prolapse	6	0.854	0.865 Question 54
Domain Micturition Pattern	16	0.734	0.769 Question 63
Domain Urinary Incontinence	16	0.880	0.883 Question 78d
Domain Obstructive Micturition	12	0.734	0.740 Question 90
Domain Defecation Pattern	9	0.704	0.722 Question 95
Domain Fecal Incontinence	23	0.859	0.866 Question 108
Domain Constipation	7	0.733	0.746 Question 127
Domain Pelvic Floor Pain	11	0.799	0.821 Question 136
Domain Sexual Dysfunction	6	0.580	0.598 Question 137

Table 13. Information Value of Items

Item Number	Wilcoxon Rank Sums Test (z=ordinal data questions) Kruskal-Wallis Test (Chi-Squared=discreet data questions)	P-value
51	Z=3.6004	P=0.0003
52	Z=3.0194	P=0.0025
53	Z=3.5153	P=0.0004
54	Z=1.8206	No Significance
55	Z=3.6596	P=0.0003
56	Z=4.1050	P<.0001
57	Z=2.5316	P=0.0114
58	Z=2.2754	P=0.0229
61a	Chi-Squared=1.4400	No Significance
61b	Chi-Squared=3.2727	No Significance
61c	Chi-Square=0.3601	No Significance
61d	Chi-Square=4.1667	P=0.0412
62	Z=-3.5197	P=0.0004
63	Z=-1.6356	Not Significant
64	Z=3.6836	P=0.0002
65	Z=-0.9560	Not Significant
66	Z=0.2291	Not Significant
67	Z=2.9953	P=0.0027
68	Z=3.4342	P=0.0006
70	Z=2.6095	P=0.0091
71	Z=3.3436	P=0.0008
72	Z=5.2386	P<0.0001

73	Z=4.0426	P<0.0001
74	Chi-Square=10.9276	P=0.0009
75	Z=4.8484	P<0.0001
76	Z=4.8761	P<0.0001
77	Z=3.6932	P<0.0002
78a	Chi-Square=8.1667	P=0.0043
78b	Chi-Square=9.4697	P=0.0021
78c	Chi-Square=20.3840	P<0.0001
78d	Chi-Square=0.3436	Not Significant
78e	Chi-Square=1.3825	Not Significant
78f	Chi-Square=16.0256	P<0.0001
78g	Chi-Square=1.0417	Not Significant
79a	Chi-Square=5.4825	P=0.0192
79b	Chi-Square=12.2500	P=0.0005
79c	Chi-Square=5.8275	P=0.0158
79d	Chi-Square=13.5624	P=0.0002
80	Z=4.4434	P<0.0001
81	Z=4.0631	P<0.0001
82	Z=2.9451	P=0.0016
83	Z=3.5683	P=0.0002
84	Z=1.4987	Not Significant
85	Z=0.9579	Not Significant
86	Z=2.1382	P=0.0325
87	Z=2.4314	P=0.0150
88	Z=4.7737	P<0.0001
89	Z=4.9706	P<0.0001
90	Z=0.0000	Not Significant

91	Z=1.3586	Not Significant
92	Z=3232.00000	P<0.0001
93	Z=6.1902	P<0.0001
94	Z=1.1773	Not Significant
95	Z=1.3838	Not Significant
96	Z=-1.1749	Not Significant
97	Z=1.2706	Not Significant
98	Z=1.9763	P=0.0481
99	Z=2.4876	P=0.0129
100	Z=2.1129	P=0.0346
101	Z=2.2262	P=0.0260
102	Z=1.0392	Not Significant
103	Chi-Square=10.9812	P=0.0009
104	Z=2.8927	P=0.0038
105	Z=3.4859	P=0.0005
106	Z=4.3371	P<0.0001
107a	Chi-Square=2.8369	Not Significant
107b	Chi-Square=1.0101	Not Significant
107c	Chi-Square=2.0408	Not Significant
107d	Chi-Square=2.0408	Not Significant
107e	Chi-Square=2.0408	Not Significant
107f	Chi-Square=11.9601	P=0.0005
108	Z=-0.0583	Not Significant
109	Z=2.9242	P=0.0035
110	Z=2.7925	P=0.0052
111	Z=2.8877	P=0.0039
112	Z=2.5183	P=0.0118

113	Z=3.2920	P=0.0010
114	Z=3.5332	P=0.0004
115	Z=2.7198	P=0.0065
116	Z=2.5040	P=0.0123
117	Z=2.7544	P=0.0059
118	Z=1.6178	Not Significant
119	Z=2.8580	P=0.0043
120	Z=3.3428	P=0.0008
121	Z=2.5978	P=0.0094
122	Z=2.0070	P=0.0448
123	Z=3.0532	P=0.0023
124	Z=2.5173	P=0.0118
125	Z=2.4803	P=0.0131
126	Z=2.4006	P=0.0164
127	Z=4.5934	P<0.0001
128	Z=1.3206	Not Significant
129	Z=2.1811	P=0.0292
130	Z=2.8438	P=0.0045
131	Z=2.6600	P=0.0078
132	Z=1.7627	Not Significant
133	Z=2.1427	P=0.0321
134	Chi-Square=7.9191	P=0.0049
134a	Chi-Square=3.1746	Not Significant
134b	Chi-Square=15.4286	P<0.0001
135	Z=5.5054	P<0.0001
136	Z=5.0791	P<0.0001
137	Z=2.4825	P=0.0130

138	**Z=1.3102**	**Not Significant**
139	**Z=3.2591**	**P=0.0011**
140	**Z=1.3877**	**P=0.0842**
144	**Z=5.2339**	**P<0.0001**
145	**Z=5.0918**	**P<0.0001**

TABLE LEGENDS

Table 1. Patient Versus Control Group Comparisons

This table summarizes the comparisons between patients and control participants with regard to demographics (age, work status and sexual partner status), lifestyle habits (smoking status and quantity of alcohol and caffeinated beverage consumption), dietary factors (eating habits including fiber and fluid intake), overall health status (height, weight and body mass index (BMI) of participants, current medical care of participants and presence of medical conditions), as well as gynecologic and obstetrical history (birth histories of participants including number of pregnancies, birth weights of babies, vaginal and cesarean section deliveries, superficial and severe perineal tearing, use of medical interventions such as episiotomy, vacuum extraction, forceps, medical and surgical induction, as well as menstruation status and presence of menopausal symptoms). The significant findings are emphasized in light grey highlight, with the non-significant findings shadowed in dark grey, for ease of visual comparison.

Comparisons were made between patients and control participants using either parametric or nonparametric tests determined by the level of data collected. For continuous data, independent t-tests were used with $p<0.05$ benchmarked to determine significance. If significant variability and inequality was noted between the groups, then Satterthwaite t-test values were used, however, if equality of between-group variability was noted, then Pooled t-test values were used. For ordinal level data Mantel-Haenszel Chi-Squared testing was used for trend testing. Categorical-level data was analyzed

using Chi-Squared testing. The nonparametric tests also followed $p<0.05$ for determining significant findings. It should be noted that some participant-characteristic categories were not included within this table as data counts within individual cells were too low to produce a valid test.

Demographics

No significant difference in age was noted between the two groups as the overall mean age of the control participants totaled 48.78 ± 16.52, compared to the similar mean age of the patient participants of 52.86 ± 13.32. There were however, some differences within the breakdown of the age categories with the most notable difference found in the '50-59' year old group containing 20 patients compared to only 7 control participants. Less notable differences were seen in age categories '20-29' years (3 patients, 9 control participants), '30-39' years (5 patients, 9 control participants), and category '60-69' years of age (8 patients, 11 control participants). Identical matching of age in years was noted in categories '40-49' (both groups containing 8 individuals), '70-79' (both groups containing 5 individuals), and '80-89' (both groups containing a single individual).

No significant difference in work status was noted between the two groups with very similar matching noted between each category. The two groups showed some differences within the 'part-time' category (6 patients, 11 control participants), and less notable differences within the categories 'disability' (3 patients, 0 control participants), and 'early-retirement' (4 patients, 1 control participant). The categories 'full-time' (17 patients, 20 control participants), 'housewife' (6 patients, 7 control participants), 'student' (2 patients and no control participants), 'retirement' (11 patients, 10 control

participants), and ‘unemployed’ (both categories containing a single individual), were all similarly matched. The overall work status was found comparable between the two groups.

Sexual partner categories were all similar with the majority of both groups having male partners (43 patients, 48 control participants), no same-sex relations noted in either the patient or control group, and a small percentage of both groups having no sexual partner (7 patients, 2 control participants) at this time. Overall, the sexual partner data was found comparable between the two groups.

Lifestyle

This section of table 1 summarizes the similarity in lifestyle habits between the groups with no significant findings noted in the comparisons. The two groups showed significant similarity within all smoking categories. The categories ‘current-smoker’ (both groups containing 7 individuals), ‘past-smoker’ (18 patients, 13 control participants) as well as ‘never-smoked’ (25 patients, 30 control participants), were all similarly matched. The overall smoking status was found comparable between the two groups, as was the glasses of alcohol consumed per day (1.51 ± 2.09 for the patients compared to 1.87 ± 2.26 for the control group), cups of caffeinated coffee and tea (1.88 ± 2.30 for the patients compared to 2.23 ± 1.58 for the control participants), and caffeinated soda (0.385 ± 1.03 for patients compared to 0.11 ± 0.34 for the control group) consumed per day.

Activity levels of the participants were also compared and found to be similar overall, as no significant difference was found. Activity episodes of a minimum of 30-minutes of exercise such as walking, gardening, swimming, etc. were tallied. The two groups showed almost identical matching for the '1 time per week' category (1 patient, 2 control participants), and some differences for the remaining categories with the control participants more highly represented in the '2 to 4 times per week' (17 patients, 21 control participants), and 'daily' activity (15 patients, 19 control participants) categories, and the patients higher in the 'never' (4 patients, 1 control participants) and 'irregularly' exercise (13 patients, 7 control participants) categories.

Dietary Factors

This section of the table summarizes the similarity in eating habits between the overall patient population versus the control population studied. The two groups showed no significant differences within either the 'eat regularly' (47 patients, 48 control participants) category or the 'eat high fiber foods' (44 patients, 45 control participants) category. Both categories were all similarly matched. The overall eating habits were found comparable between the two groups, as were the overall fluid intake levels. With regard to fluid intake, the two groups showed some differences within the 'less than 4 cups per day' (3 patients, 0 control participants), '4 to 6 cups per day' (16 patients, 23 control participants), and 'greater than 8 cups per day' (13 patients, 9 control participants) categories and identical findings in the '6 to 8 cups per day' (18 patients, 18 control participants). The overall fluid intake was found comparable between the two groups.

Overall Health

The overall health status of the two groups was found to be significantly different ($p=0.0181$), as was the use of medical specialists ($p=0.0004$), participants under the care of a gynecologist ($p=0.0218$), the presence of vascular disease ($p=0.0018$), back pain ($p=0.0009$), and the presence of other major illness ($p<0.0001$). Otherwise, this section of the table shows no significant differences between the two groups for 'height', 'weight', 'body mass index', care of 'cardiology', 'endocrinology', 'oncology', 'internist', 'surgeon', 'gastroenterology', or 'other health care providers'. There were also no significant differences found between the presence of 'diabetes', 'heart conditions' or 'lung conditions'. The two groups showed notable differences within the 'urologic surgery' (5 patients, 0 control participants), 'general surgery' (36 patients, 26 control participants), and 'gynecologic surgery' (30 patients, 19 control participants) categories and less notable differences within the category 'orthopedic surgery' (9 patients, 6 control participants). The categories 'thoracic surgery' (2 patients, 3 control participants), 'no surgery' (0 patients, 0 control participants), and 'mean total surgery' were all similarly matched. The overall surgical mean for the patient participants was 1.64, compared to a mean total of 1.08 for the control participants. Interestingly, every participant, regardless of group, had previously undergone surgery.

Gynecologic & Obstetrical History

Throughout the gynecological and obstetrical history section of this table, some significant differences were noted between the two groups; however, the overall similarity was surprisingly notable. Possibly the most interesting similarities noted were in the number of pregnancies, birth weights of babies, mode of delivery, tearing of the perineum, and instrumental usage during delivery.

Regarding the number of pregnancies of the participants, while the two groups showed differences within the separate categories, these differences fluctuated with patients higher in some categories and control participants higher in neighboring categories. Overall, this created a balanced effect and produced similar matching in overall mean number of pregnancies (patients 2.26, control participants 2.08). Notable findings include the significant difference of 12 control participants never having been pregnant compared to only 5 of the patients (offset by 6 patients and only 1 control participant having only a single pregnancy), and 12 of the patients having 4 or more pregnancies with only 6 of the control participants filling this category. This was offset by the 16 control participants having birthed 3 babies, with only 6 patients filling this category. Similarity was noted between the groups for the '2 pregnancies' category, with 20 patients and 15 controls applicable. The overall pregnancy history was found comparable between the two groups.

The overall birth weights of the participants' babies was another comparison showing surprisingly non-significant differences. The two groups showed notable similarity in all categories from 6 pounds and higher. The category '6 pounds to 6 pounds 15 ounces' was filled with 22 patients compared to 18 control participants, 32

patients compared to 33 control participants filled the category ‘7 pounds to 7 pounds 15 ounces’, 23 patients and 24 control participants completed category ‘8 pounds to 8 pounds 15 ounces’, 11 patients and 8 control participants filled category ‘9 pounds to 9 pounds 15 ounces’, and 3 patients compared to 2 control participants filled category ‘10 pounds or greater’. For the ‘less than 5 pounds’ and ‘5 pounds to 5 pounds 15 ounces’ categories, there were some differences noted as 3 patients compared to 1 control participant reported births of babies ‘less than 5 pounds’. This, however, was somewhat balanced off with the neighboring category of ‘5 pounds to 5 pounds 15 ounces’ showing 7 control participants and 0 patients. Overall, the lack of symmetry at this end of the spectrum was overshadowed by equality within every category 6 pounds and greater. The mean birth weight of babies was 8 pounds 7.52 ounces for the patient population and 7 pounds 9.44 ounces for the control population for a difference of 14.08 ounces between the means of the two groups. The overall birth weight of participants’ babies was found comparable between the two groups.

Mode of delivery, vaginal versus cesarean section births, use of forceps, vacuum extraction and induction, and superficial and severe tearing during delivery showed no significant differences, when the groups were compared. There were, however, differences noted between the two groups in use of episiotomy as well as the amount of time spent pushing during labour. For the menstruation status of the two groups, while no significance was found between the two groups for numbers of individuals still menstruating versus those experiencing menopause, there were significantly more menopausal symptoms noted for the patient group versus the control group.

No Significant Differences Noted

No significance was noted in most of the characteristic comparisons such as age, work status, sexual partner, current and past smoking status, alcohol consumption, caffeinated coffee and tea consumption, caffeinated soda consumption, regularity in eating habits, fiber intake in diet, fluid intake, height, weight and BMI of participants, participants currently under the care of a cardiologist, endocrinologist, oncologist, internist, surgeon, gastroenterologist or other health specialists, presence of other medical conditions such as diabetes, heart and lung conditions, number of pregnancies, birth weights of babies, vaginal births, cesarean section births, use of vacuum extraction, forceps and induction, superficial and severe tearing of the perineum, and menstruation status.

Significant Differences Noted

There were however, significant findings in overall health status between the two groups, with a Mantel-Haenszel Chi-Squared value=5.5818, p=0.0181. As well, when comparing the use of medical specialists, highly significant findings were noted with a Chi-Squared value of 12.7033, p=0.0004. Specifically, the care of gynecology was a discipline that showed significant findings, as Chi-Squared testing produced a value of 5.2632, p=0.0218. Regarding specific medical conditions, significance was noted for vascular conditions, Chi-Squared=9.7561, p=0.0018, and the presence of back pain was highly significant, with Chi-Squared=11.1111, p=0.0009. Overall, the presence of other

major medical illness or disorder was also found to be highly significant, with Chi-Squared=18.2307, $p<0.0001$.

With regard to gynecologic and obstetrical history, episiotomy use was compared between the patient population and the control population, and significant findings of Chi-Squared=8.3580, $p=0.0392$ were found. Another area discerning the two groups was noted with comparison of the length of time spent pushing during vaginal delivery. The two groups showed notable differences within the '15 minutes' category with 18 control participants filling this category compared to only 10 patients reporting this short period of pushing during labour. As well, the longest period of pushing during labour, the 'greater than 60 minutes' category, was represented with 12 patients compared to only 6 control participants. Less notable differences were found within the categories '30 minutes' (6 patient, 8 control participants), '45 minutes' (4 patients, 1 control participant), and '60 minutes' (3 patients, 1 control participant). Overall, a dramatic difference was noted on both ends of the spectrum with 26 of the control participants compared to 10 patients having pushed 30 minutes or less, while only 8 control participants, compared to 19 patients, reported pushing for 45 minutes or more, during their labours. The Mantel-Haenszel Chi-squared p-value of 0.0191 supports a significant difference in the overall length of time spent pushing during vaginal labour for two groups, with the patient population pushing significantly longer than the control population. Finally, this table also illustrates the highly significant finding that menopausal symptoms are of greater concern within the patient population compared to the control population, as Chi-Squared=21.5686, $p<0.0001$.

Table 2. Symptoms in Bladder Domains

This table summarizes the numbers of participants showing dysfunction within the three domains related to the bladder organ; domain Micturition Pattern, domain Urinary Incontinence and domain Obstructive Micturition. The results of the completed questionnaires revealed that of the n=50 patients studied, 5 experienced symptoms of decreased daytime urinary frequency and 1 of increased daytime urinary frequency. Of the n=50 control participants, 7 experienced decreased daytime urinary frequency and 9 displayed symptoms of increased frequency of daytime voiding. Interestingly, the control participants presented with more symptoms of urinary frequency than the patients for both categories. Review of the data for nighttime voids shows that 28 of the patients and 27 of the control participants voided 1-2 times per night and 8 patients and 2 control participants voided 3-4 times per night. Additionally, 1 patient reported the need to void greater than 4 times each night. Analysis of responses to bladder urgency questions revealed that 1 patient and zero control participants suffered with constant bladder demands of feeling the need to void. For the category of urgency occurring less than every 2 hours, 25 patients and 10 control participants reported these symptoms. As well, a delay in feelings of bladder urgency was noted in 3 patients compared to 5 control participants.

For domain Urinary Incontinence, 43 of the 50 patients reported symptoms of urinary incontinence. Of the 50 control participants, 28 described experiences with urinary incontinence. For evaluation of domain Obstructive Micturition, with regard to a feeling of incomplete bladder emptying following voiding, 21 patients versus 8 control

participants reported this symptom. Furthermore, 17 patients compared to 14 control participants note urinary dribbling upon rising from voiding.

Table 3. Poor Toileting Biomechanics

This table summarizes the presence of poor toileting biomechanics during voiding and defecation. Within the domain Micturition Pattern, urinary posture was evaluated as participants were asked if they sit, hover, or sit when at home and hover elsewhere, when voiding. While the presence of hovering to eliminate urine is considered a poor biomechanical voiding posture that may lead to dysfunctional symptoms, it was not considered a dysfunction within the bladder domains but rather used to detect the need for education on proper habits. In total, 9 patients and 13 control participants reported sitting to void when at home and hovering over the toilet when elsewhere.

This table also lists the harmful habit of straining with defecation, an additional poor biomechanical choice when toileting. Analysis of the questionnaires revealed that 3 patients and 1 control report the need to strain ‘regularly’ or ‘always’, for bowel movements. For those that note straining ‘seldom’ or ‘sometimes’, 37 patients and 33 control participants complete this category.

Table 4. Symptoms in Bowel Domains

This table summarizes the dysfunctions noted in the three domains related to the bowel organ; domains Defecation Pattern, Constipation and Fecal Incontinence. For the domain Defecation Pattern, 1 patient as well as 1 control reported having only a single bowel movement each week. Another notable finding in this table was that 3 patients and 1 control participant chose the 'other' category. Evaluation of reasons given for this choice, indicate that 1 of the 3 patients has an iliostomy bag to collect stool, while the remaining 2 patients reported large fluctuations in frequency of bowel movements. The single control participant choosing the 'other' category reported 5 bowel movements per day. One of the categories reflected the choice of greater than 2 bowel movements per day, and was selected by 6 patients and 4 control participants. The wording of this answer led to difficulty with data analysis as the Rome criteria lists up to 3 bowel movements per day as functional however, greater than 3 indicating abnormality. As it is impossible to determine if the answer of greater than 2 bowel movements per day reflects an acceptable number of 3 versus an inappropriate number of greater than 3, the 6 patients and 4 control participants in this category were considered to be within normal range.

Analysis of the questionnaires revealed that for domain Constipation, 6 of the 50 patients and 3 of the 50 control participants reported that they never, or seldom, feel that they have fully emptied their bowels following defecation. Also, 11 patients and 9 control participants felt that they only sometimes fully empty their bowels. For domain Fecal Incontinence, 16 patients and 3 control participants reported symptoms of fecal incontinence.

Table 5. Symptoms of Pelvic Organ Prolapse, Pelvic Floor Pain and Sexual Dysfunction

This table summarizes the dysfunctions noted in the remaining three domains; domain Pelvic Organ Prolapse, domain Pelvic Floor Pain and domain Sexual Dysfunction. For domain Pelvic Organ Prolapse, 14 patients and 4 control participants responded positively to experiencing symptoms of POP 'seldom' to 'sometimes', whereas 5 patients and 0 control participants report 'regular' to 'constant' presence of POP symptoms.

With regard to domain Pelvic Floor Pain, the presence of four separate areas of pelvic floor pain were evaluated. Anal cramping was noted by 13 patients and 3 control participants. The symptoms of perineal pain, or pain between the vagina and anus, was reported by 12 patients versus 3 control participants. Coccyx pain, often referred to as tailbone pain, was experienced by 17 patients and 10 control participants, and pain near the sit bones, or ischial tuberosities, was felt by 16 patients and 8 control participants.

Finally, for domain Sexual Dysfunction, over half (26) of the 50 patients reported pain with sexual intercourse compared to 12 of the 50 control participants. Upon further investigation, 18 patients and 10 control participants reported pain on penetration with intercourse. As well, 24 patients compared to 6 control participants reported pain deep within, during intercourse. Many participants reported both symptoms, pain with penetration as well as pain deep within, during intercourse.

Table 6. Number of Domains Patients Experienced Dysfunction

This table summarizes the multiple number of domains where patients experienced dysfunctions. Co-occurrence of pfm dysfunction is evident in this group of patients as none of the patients displayed symptoms of dysfunction in only a single domain. Of the 50 patients, 6 had dysfunctions in 2 pfm domains, 9 had 3 dysfunctional domains, 10 reported symptoms in 4 domains, 8 patients were found to have dysfunction of 5 domains, 9 patients represented 6 dysfunctional domains, 7 patients had 7 separate dysfunctions and 1 patient measured dysfunction in each of the nine pfm domains.

Of the 50 patients, 47 had a single pfm disorder for which they sought treatment and the remaining 3 patients requested treatment for 2 pfm disorders. All 50 patients (100%) indicated symptoms in domains other than the domain, or domains, for which medical treatment was sought. For the 47 patients reporting with a single dysfunctional domain, disorders were noted in between 2 to 9 domains. For the 3 patients presenting for treatment in 2 domains, dysfunction was noted in 3, 6 and 7 domains. It should be noted that 5 of the 50 patients showed dysfunctions in domains that are often related or directly connected to each other. For example, it is understandable that the patient presenting with urinary incontinence would also have symptoms in domain Micturition Pattern and domain Obstructive Micturition. The remaining 45 of the 50 patients (90%) however, noted dysfunctions in varying domains such as presenting with urinary incontinence also experiencing symptoms in bowel domains and pain domains.

Table 7. PFM Dysfunctions Detected in Control participants

This table summarizes the number of domains where control participants were represented with dysfunction. Of the 50 control participants, only 3 had no symptoms within any of the nine pfm domains. The number of control participants found to have dysfunction in a single domain was 8 (of the 8, 5 displayed dysfunctions in bladder domains, 1 had bowel dysfunction and the remaining 2 experienced sexual dysfunction). There were 11 control participants noted to have symptoms within 2 domains, 15 control participants in 3 separate domains, and 8 control participants experienced dysfunction in 4 domains. The remaining 3 control participants displayed dysfunction in 5 of the 9 pfm domains.

Table 8. Construct Validity: Domain Comparisons

This table details the findings of the Construct Validity determination between domains. Independent t-tests were used to compare each patient domain to the corresponding control domain with $p<0.05$ considered significant. T-tests were determined using both the Pooled Method and the Satterthwaite Method and as the variability between the two groups was found to be unequal, Satterthwaite data was used. All domain comparisons were found to be very significant with $p<0.0001$ for all domains with the exception of domain Defecation Pattern, where $p=0.0048$ still exceeds the critical value for significance. For all domains, means of the patients were higher than the means of the control population.

Table 9. Content Validity Evaluation

This table details the findings of the Content Validity Evaluation Questionnaire. Eight experts consisting of one urologist, one urogynecologist, one gynecologist, two colorectal surgeons and three sexual medicine/pelvic pain specialists completed the content validity questionnaire for assessment of the English-language PelFIs questionnaire. Each of the 9 domains plus the medical intake portion and the document as a whole were evaluated on relevance, accuracy and omissions of questions within the section as well as the section overall. These 4 questions were evaluated on a scale of 0 to 4 with 0 reflection numerous concerns, 1 for several concerns, 2 for a few concerns, 3 corresponding to a single concern and 4 being no concerns with the questions.

The lowest evaluation scores were noted in the Medical Intake portion of the document with a mean score of 2.594 with a perfect score being 4.000. The 4 areas of measurement within this section ranged between 2.500 for 'accuracy of questions' (falling midpoint between 2 reflecting 'a few concerns with accuracy' and a score of 3 correlating with 'a single area of concern with accuracy') to 2.875 for 'relevance of questions' (with 2 reflecting a relevance of questions rating of 'satisfactory' and 3 being 'very relevant').

The domain Pelvic Organ Prolapse showed a mean evaluation of 3.000 out of 4.000. The four areas of evaluation for this domain ranged between 2.667 for 'relevance of questions' and 3.167 for both 'accuracy of questions' (3 reflects 'a single area of concern with accuracy' and 4 being 'no inaccuracies noted') and 'omissions of questions' (3 reflects 'a single concern of omission' and 4 being 'no omissions noted, section fully complete').

Bladder function relates specifically to 3 of the 9 domains. The domain Micturition Pattern showed a mean evaluation of 3.428 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.143 for 'omissions of questions' and 3.571 for both 'relevance of questions' and 'accuracy of questions'. The domain Urinary Incontinence showed a mean evaluation of 3.607 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.286 for 'omissions of questions' and 3.857 for 'accuracy of questions'. The domain Obstructive Micturition showed a mean evaluation of 3.500 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.143 for 'relevance of questions' and 3.857 for 'omissions of questions'.

The following 3 domains relate specifically to bowel function. The domain Defecation Pattern showed a mean evaluation of 3.625 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.375 for 'omissions of questions' and 4.000 for 'accuracy of questions'. The domain Fecal Incontinence showed a mean evaluation of 3.781 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.750 for 'relevance of questions', 'accuracy of questions' and 'section rated overall', and 3.875 for 'omissions of questions'. The domain Constipation showed a mean evaluation of 3.719 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.625 for 'relevance of questions', 'omissions of questions' and 'section rated overall', and 4.000 for 'accuracy of questions'.

The following 2 domains relate to pelvic pain and sexual dysfunction. The domain Pelvic Floor Pain showed a mean evaluation of 3.281 out of 4.000. The 4 areas of evaluation for this domain ranged between 3.000 for 'omissions and questions' and 3.500 for 'accuracy of questions'. The domain Sexual Dysfunction showed a mean

evaluation of 2.750 out of 4.000. The 4 areas of evaluation for this domain ranged between 2.571 for ‘omissions of questions’ and ‘section rated overall’ and 3.000 for ‘accuracy of questions’.

The document as a whole was also rated. The English-language PelFIs questionnaire showed a mean evaluation of 2.750 out of 4.000. The 4 areas of evaluation for the document as a whole ranged between 2.625 for ‘accuracy of questions’, ‘omissions of questions’ and ‘section rated overall’, up to 3.125 for ‘relevance of questions’. When analyzing the 4 areas of evaluation, the ‘relevance of questions’ mean rating equaled 3.291, ‘accuracy of questions’ mean rating equaled 3.400, ‘omissions of questions’ mean rating equaled 3.199 and ‘section rated overall’ mean rating equaled 3.214.

Table 10: Test-Retest Reliability

This table represents the comparison the subsample data of 25 patients from time-one to time-two to determine test-retest reliability using Intraclass Correlation Coefficients (ICC) with the acceptable coefficient for group differences being ICC=0.70. The significant findings are emphasized in light grey highlight, with the non-significant findings shadowed in dark grey, for ease of visual comparison. The patient subsample data was analyzed by looking at the association between time-one to time-two for all domains combined, as well as for each of the nine domains individually for measurement of correlation. When all domains inclusively compared, a very high ICC of 0.905($p<0.0001$) was attained. For comparisons of the domains individually, 8 of the

9 domains were shown to exceed the ICC=0.70 critical value. Domain Urinary Incontinence fell slightly short of this benchmark, with ICC=0.692. The ICC values of the 8 significant domains ranged between ICC=0.774 ($p<0.0001$) for domain Constipation, up to ICC=0.921 ($p<0.0001$) for domain Pelvic Organ Prolapse.

Table 11. Pearson Correlation Coefficients

This table represents the inter-correlations between the 9 domains of the English-language PelFIs, using r=0.70 to determine significance. Significant correlation between domain Urinary Incontinence and domain Obstructive Micturition was determined with r=0.72324 ($p<0.0001$). Domain Constipation was found to be significantly correlated with domain Pelvic Pain with r=0.73703 ($p<0.0001$), and finally domain Pelvic Pain and domain Sexual Dysfunction were highly correlated with r=0.87025 ($p<0.0001$). Additionally, there were 4 domain correlations that while not meeting the r-value to be considered significant, should be recognized for approaching the necessary criteria. These connected domains were domain Micturition Pattern and domain Obstructed Micturition, with r=0.66910 ($p<0.0001$), domain Defecation Pattern and domain Fecal Incontinence with r=0.67937 ($p<0.0001$), combined domains Constipation and Defecation Pattern with r=0.68081 ($p<0.0001$), and finally domain Constipation and domain Fecal Incontinence with r=0.66929 ($p<0.0001$).

Table 12. Cronbach's Alpha for Domains

This table summarizes the Cronbach's alpha determined for each of the 9 domains. Alpha values equal or greater than 0.70, were considered significant and reflects that all items within the domain are co-varying to the same degree. The significant findings are emphasized in light grey highlight, with the non-significant findings shadowed in dark grey, for ease of visual comparison. Of the 9 domains, 8 exceeded the significant value with only domain Sexual Dysfunction falling short with alpha=0.580. Even with the removal of 1 of the 6 items within domain Sexual Dysfunction, the increased alpha of 0.598 would not reach significance. For the remaining domains, the removal of a single suggested item would further increase the alpha value as well as assist in reducing the large number of items within this document.

Table 13. Information Value of Items

This table summarizes the results of the Wilcoxon Rank Sum and Chi-Squared tests used to analyze the patient responses against the control responses to each individual question within the document. If significant difference was noted between the two groups, then this item was deemed highly useful and beneficial to the minimum data set. Those questions not showing significant difference between patients and control participants were considered relatively less informative and marked for consideration of removal in future PelFIs editions. The significant findings are emphasized in light grey highlight, with the non-significant findings shadowed in dark grey, for ease of visual comparison. The following 30 items on the English-language PelFIs were determined to

be relatively less informative; questions 54, 61a, 61b, 61c, 63, 65, 66, 78d, 78e, 78g, 84, 85, 90, 91, 94, 95, 96, 97, 102, 107a, 107b, 107c, 107d, 107e, 108, 118, 128, 132, 134a and 138.

REFERENCES

(1) Voorham-van der Zalm PJ, Stiggelbout AM, Aardoom I, Deckers S, Greve IG, Lycklama a Nijeholt GAB, Pelger RCM. Development and Validation of the pelvic floor inventories Leiden (PelFIs). Neurourol.Urodyn. 2008;27(4):301-305.

(2) Wirthlin Worldwide. International Continence Society multi-national survey: Stress urinary incontinence and women: discovering the truth. 2003.

(3) Mayo Clinic. What is urinary incontinence? [Online]. 2002 [cited 2002 Jun 9]. Available from: URL: http://www.mayoclinic.com/findinformation/conditioncenters/invoke.cfm?objectid=256654C2-9

(4) Morin, M., Bourbonnais, D., Gravel, D., Dumoulin, C., & Lemieux, M-C. Pelvic floor muscle function in continent and stress urinary incontinent women using dynamometric measurements. Neurourol.Urodyn. 2004;23(7):668-674.

(5) Prather H, Spitznagle TM, Dugan SA. Recognizing and treating pelvic pain and pelvic floor dysfunction. Phys Med Rehabil Clin N Am. 2007 Aug;18(3):477-496.

(6) Nitti VW. Clinical Impact of Overactive Bladder. Rev. Urol. 2002; 4(supp 4):S2-S6.

(7) Zutshi M, Hull TL, Bast J, Hammel J. Female bowel function: the real story. Dis Colon Rectum. 2007 Mar;50(3):351-358.

(8) Stewart, WF, Liberman JN, Sandler RS, Woods MS, Stemhagen A, Chee E, Lipton RB, Farup CE. Epidemiology of constipation (EPOC) study in the United States: relation of clinical subtypes to socioeconomic features. Am J Gastroenterol. 1999; 94:3530-3539.

(9) Iantorno G, Cinquetti M, Mazzocchi A, Morelli A, Bassotti G. Audit of Constipation in a Gastroenterology Referral Center. Dig Dis Sci 2007;52:317-320.

(10) Shull BL. Pelvic organ prolapse: anterior, superior, and posterior vaginal segment defects. Am J Obstet Gynecol 1999;181:6-11.

(11) Slieker-ten Hove MCP, Vierhout M, Bloembergen H, Schoenmaker G. Distribution of pelvic organ prolapse (POP) in the general population; prevalence, severity, etiology and relation with the function of the pelvic floor muscles. Neurourol.Urodyn. 2004;23(5/6):401-402.

(12) Dietz HP. The aetiology of prolapse. Int Urogynecol J 2008;19:1323-1329.

(13) Wenof M, Perry CP. Chronic pelvic pain. A patient education booklet. The International Pelvic Pain Society. 1999.

(14) Travell J, Simons D. Myofascial pain and dysfunction: the trigger point manual. Baltimore (MD): Williams & Wilkins; 1992:110-131.

(15) Laumann EO, Paik A, Rosen RC. Sexual Dysfunction in the United States. JAMA 1999;281 (6):537-544.

(16) Rosen RC, Taylor JF, Leiblum SR, Bachmann GA. Prevalence of sexual dysfunction in women: results of a survey study of 329 women in an outpatient gynecological clinic. J Sex Marital Ther. 1993 Fall;19(3):171-188.

(17) Gordon D, Groutz A, Sinai T, Wiezman A, Lessing JB, David MP, Aizenberg D. Sexual function in women attending a urogynacology clinic. Int Urogynecol J 1999;10:325-328.

(18) Handa VL, Harvey L, Cundiff GW, Siddique SA, Kjerulff KH. Sexual function among women with urinary incontinence and pelvic organ prolapse. Am J Obstet Gynecol 2004;191:751-756.

(19) Barber MD, Visco AJ, Wyman JF, Fantl JA, Bump RC. Sexual function in women with urinary incontinence and pelvic organ prolapse. Obstet Gynecol 2002;99:281-289.

(20) Messe MR, Greer JH. Voluntary vaginal musculature contractions as an enhancer of sexual arousal. Arch Sex Behav 1985;14:13-28.

(21) Dean N, Wilson D, Herbison P, Glazener C, Aung T, MacArther C. Sexual function, delivery mode history, pelvic floor muscle exercises and incontinence: A cross-sectional study six years post-partum. Aust N Z J Obstet Gynaecol 2008; 48:302-311.

(22) Voelker R. International group seeks to dispel incontinence “taboo”. JAMA 1998;280(11):951-953.

(23) Grimby A, Milsom I, Molander U, Wiklund I, Ekelund P. The influence of urinary incontinence on the quality of life of elderly women. Age Ageing 1993 Mar;22(2):82-89.

(24) Overactive bladder, a medical condition many struggle with needlessly. UniDet. 2002 Oct. Backgrounder. Decima Research Poll, May 2002.

(25) Nygaard I, Barber MD, Burgio KL, Kenton K, Meikle S, Schaffer J, Spino C, Whitehead WE, Wu J, Brody DJ. Prevalence of symptomatic pelvic floor disorders in US women. JAMA. 2008;300(11):1311-1316.

(26) Lawrence, JM, Lukacz ES, Nager CW, Hsu JW, Luber KM. Prevalence and co-occurrence of pelvic floor disorders in community-dwelling women. Obstet Gynecol 2008 Mar;11(3):678-685.

(27) Rogers RG, Kammerer-Doak D, Villarreal A, Coates K, Qualls, C. A new instrument to measure sexual function in women with urinary incontinence or pelvic organ prolapse. Am J Obstet Gynecol 2001;184:552-558.

(28) Reese PR, Pleil AM, Okano GJ, Kelleher CJ. Multinational study of reliability and validity of the King’s Health Questionnaire in patients with overactive bladder. Qual Life Res 2003;12:427-442.

(29) Barber MD, Kuchibhatla MN, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. Am J Obstet Gynecol 2001;185:1388-1395.

(30) Radley SC, Jones GL, Tanguy EA, Stevens VG, Nelson C, Mathers NJ. Computer interviewing in urogynaeology: Concept, development and psychometric testing of an electronic pelvic floor assessment questionnaire in primary and secondary care. BJOG 2006;113:231-238.

(31) Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. Qual Life Res 1994;3:291-306.

(32) So you want to use a Likert scale? Learning technology dissemination initiative. [Online]. [cited 2008 Sep 7]. Available from: URL: http://www.icbl.hw.ac.uk/ltdi/cookbook/info_likert_scale/index.html

(33) Komorita S. Attitude content, intensity, and the neutral point on a Likert scale. Journal of Social Psychology 1963;61:327-334.

(34) MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. BJOG 2000;107:1460-1470.

(35) Voorham-van der Zalm PJ, Lycklama a Nijeholt GAB, Elzevier HW, Putter H, Pelger RCM. Diagnostic investigation of the pelvic floor: a helpful tool in the approach in patients with complaints of micturition, defecation, and/or sexual dysfunction. J Sex Med 2008;5:864-871.

APPENDIX I: Script for Recruiting Patient Participants

Thank you for booking your appointment for your initial assessment.

The pelvic floor physiotherapists at this clinic are involved in a research study with the University of Manitoba. They are testing the validity of a new pelvic floor dysfunction questionnaire.

Most of the questions on this new form are the same questions that your physiotherapist would be asking you during your assessment.

Would you consider participating in this research study by signing a consent form, allowing your physiotherapist to ask these questions and record them on this new form?

Your answers would be used for your assessment and also anonymously they would be used in research to test if the questionnaire is valid.

You are under no obligation to participate and this would never affect your treatment at the clinic.

For those patients verbally agreeing to participate in the research study or those requesting further information:

This research study has a second component to it and again, you are under no obligation to participate in this second section. Would you be interested in attending the clinic at least 2-weeks before your first appointment to complete this 20-30 minute questionnaire with a physiotherapist?

This is the same questionnaire that you will complete at your first appointment but it will be given by a different physiotherapist.

To thank you for coming down to the clinic for this part of the study, you would receive $5.00 for parking or bus fair, plus a complementary copy of the book *I Laughed So Hard I Peed My Pants! A Woman's Essential Guide for Improved Bladder Control.* Valued at $30.00.

APPENDIX II: Advertising Poster

VOLUNTEERS REQUIRED FOR RESEARCH TO STUDY THE VALIDITY OF A PELVIC FLOOR QUESTIONNAIRE

Volunteers are required for a research study to be conducted through the School of Medical Rehabilitation. We are looking for healthy female individuals who are not taking medications and have not sought medical treatment for pelvic floor problems.

This study is being conducted to evaluate the validity and reliability of the English-Language version of the Dutch Pelvic Floor Inventories Leiden (PelFIs) Administered Questionnaire.

Participants will be required to attend one session lasting approximately 20 to 30 minutes.

Interested volunteers please contact:

Kelli Berzuk	**Or**	**Dr. Barbara Shay**
MSc Candidate		**Associate Professor**
School of Medical Rehab		**School of Medical Rehab**
982.9178		**787.2756**

APPENDIX III: English-Language PelFIs

Questionnaire (female)

Number:_____

1. Date of birth: _____/_____/_____
2. Date of registration _____/_____/_____
3. Indication _____

4. Description of symptoms: What does the patient complain of? Specific description given by the patient.
   _____
   _____
   _____
5. Cause:
   a. parturition (childbirth)
   b. congenital disorder
   c. accident/trauma
   d. urological operations
   e. surgical operations
   f. gynecological operations
   g. menopause
   h. not known
6. Duration of complaint:
   a. less than half a year
   b. 6 to 12 months
   c. 1 to 2 years
   d. longer than 2 years

General Health of Patient

7. How would you describe your general health?
   a. excellent
   b. very good
   c. good
   d. moderately good
   e. poor
8. a. height in cm:_____
   b. weight in kg:_____

9. Work status:
    a. full-time
    b. part-time
    c. housewife
    d. on disability/sick benefits
    e. student
    f. pensioner/retired
    g. early retirement
    h. unemployed

10. Occupation/What sort of work do you do? _____
    _____
11. Do you live
    a. independently?
    b. in a sheltered accommodation?
    c. in a care home?
    d. with parents?
    e. with support?
12. Have you a partner?
    a. yes, male
    b. yes, female
    c. no
13. Do you smoke?
    a. yes
    b. no
14. How long have you smoked for? _____
    a. How many cigarettes on average per day? _____
    b. How many cigars on average per day? _____
    c. Not applicable
15. If not, have you ever smoked?
    a. yes
    b. no
16. If so, when did you stop smoking? _____
    a. How many cigarettes did you smoke on average per day? _____
    b. How many cigars did you smoke on average per day? _____
17. Has stopping smoking influenced your complaints?
    a. yes
    b. no
18. If so, in what way? _____

19. Do you drink alcohol?
    a. yes
    b. no
20. If so, how many glasses average per weekday? _____
21. How many glasses on average at the weekend? _____
22. How many cups of coffee do you drink on average per day? _____
23. How many glasses of Cola do you drink on average per day? _____

24. Are you currently receiving treatment from other specialists? Yes No
If so, which?
    a. cardiologist
    b. gynaecologist
    c. endocrinologist
    d. oncologist
    e. internist (general medicine)
    f. surgeon
    g. gastroenterologist
25. Do you suffer from diabetes? Yes No
26. Does it occur in your family? Yes No
27. Do you suffer from heart problems? Yes No If yes, what? _____
28. Do you have blood vessel problems? Yes No If yes, what? _____
29. Do you have back pain at present? Yes No
30. Do you have lung problems? Yes No
31. Do you have any other disorders? Yes No
32. Are you taking any medication? Yes No
    a. yes, for the lungs. Which? _____
    b. yes, for the heart. Which? _____
    c. yes, for bladder problems. Which? _____
    d. yes, for bowel problems. Which? _____
    e. yes, antidepressants. Which? _____
    f. yes, painkillers. Which? _____
    g. yes, contraception. Which? _____
    h. others.
    i. none.
33. What operations have you had in the past?
    a. urological. Which? _____
    b. surgical. Which? _____
    c. gynaecological. Which? _____
    d. orthopaedic.
    e. thoracic.
    f. none.
34. Do you eat regularly? Yes No
35. Do you eat plenty of fibre? Yes No
36. How much liquid do you drink on average per weekday?
    a. less than one litre per day
    b. 1 to 1.5 litres per day
    c. 1.5 to 2 litres per day
    d. more than 2 litres per day
37. Are you physically active—cycling, walking, gardening, sport?
    a. never
    b. yes, daily for ½ an hour or more
    c. yes, 2 to 4 times per weeks
    d. yes, every week
    e. irregularly

38. Are you pregnant at the moment?
    a. yes
    b. no
    c. not applicable
39. Are you trying to have children?
    a. yes
    b. no
    c. not applicable

40. How many pregnancies have you had?
    a. 1
    b. 2
    c. 3
    d. 4 or more
    e. not applicable
    f. none
41. How many times have you given birth without a Caesarean section? _____
42. How many times have you given birth with a Caesarean section? _____
43. How long ago was that? _____
44. Did you suffer tearing during the delivery?
    a. yes, severe tearing
    b. yes, superficial tearing
    c. no
    d. not applicable
    e. not known

45. Did you have an episiotomy during the delivery?
    a. yes
    b. no
    c. not applicable
    d. not known

46. How heavy were your children?
    a. child 1 _____g
    b. child 2 _____g
    c. child 3 _____g
    d. child 4 _____g
    e. child 5 _____g

47. Were the following methods used during the delivery?
    a. vacuum extraction (ventouse)
    b. forceps delivery
    c. medical or surgical induction
    d. none used

48. How long had you to push for during the delivery?
    a. 15 minutes
    b. 30 minutes
    c. 45 minutes
    d. 60 minutes
    e. more than 60 minutes

49. Do you still menstruate?
    a. yes, regularly (every four weeks)
    b. yes, but irregularly
    c. no, not for some months
    d. no, not for more than a year
50. Have you menopausal symptoms?
    a. yes
    b. no

Sagging feeling:

51. Do you feel vaginal swelling, a feeling of pressure, which increases during the day, tiredness, a prickling sensation, low back pain increasing with coughing, or sneezing, with exertion, bending or lifting?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always

52. Can you see vaginal swelling or observe swelling with your fingers? Is it troublesome during intercourse?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always

53. Do you notice vaginal swelling when you move your bowels?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always

54. Do you feel that mucous membrane or other tissue spontaneously comes out of your anus during running, or bowel motion?

a. never
b. seldom
c. sometimes
d. regularly
e. always

55. Does this restrict you in your work or leisure activities?

a. never
b. seldom
c. sometimes
d. regularly
e. always

56. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to the sagging feeling **at this moment.**

No discomfort Much discomfort
l----------l

0 10

Domain Micturition Pattern

57. How often on average do you pass urine during the day?

a. 2-4 times per day
b. 5-7 times per day
c. 8-10 times per day
d. more than 10 times per day

58. How often on average do you pass urine at night?

a. never
b. 1-2 times per night
c. 3-4 times per night
d. more than 4 times per night

59. Some people never feel any urgency to urinate. Do you feel this urgency to urinate?

a. yes
b. no

60. If not, when do you urinate then? _____

61. Do you notice more urgency:
    a. in the cold yes no
    b. if a tap is running yes no
    c. if you are nervous yes no
    d. in the shower yes no

62. How often do you feel the need to urinate?
    a. continually
    b. every half hour
    c. every hour
    d. longer than 1 hour
    e. 2-4 hours
    f. longer

63. Can you put off urinating if you are sitting quietly?
    a. must run directly
    b. for a few minutes
    c. have good control
    d. other. Please indicate: _____

64. Can you put off urinating if you are busy?
    a. must run directly
    b. for a few minutes
    c. have good control
    d. other. Please indicate: _____

65. How do you urinate?
    a. sitting
    b. "hovering"
    c. at home sitting, elsewhere "hovering"

66. How does the urine start?
    a. spontaneously
    b. must wait
    c. it varies
    d. other. Please indicate: _____

67. Does the urine come in one flow?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

68. Does the urine come in little bursts?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

69. Is that what you want?
    a. yes
    b. no
    c. not applicable

70. Do you have to push when you urinate?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

71. What is the flow normally like?
    a. mostly strong
    b. mostly weak
    c. mostly normal
    d. other. Please indicate: _____

72. Does this restrict you in your work or leisure activities?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always

73. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to the sagging feeling **at this moment.**

No discomfort Much discomfort
l----------l

0 10

Domain Urinary Incontinence

74. Are you ever incontinent?
    a. yes
    b. no
75. How much urine leaks?
    a. drops
    b. a small burst
    c. a whole bladder full
    d. other. Please indicate: _____
    e. not applicable

76. How often does urine leakage occur?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

77. Urine leakage day/night
    a. only in the daytime
    b. only at night
    c. day and night

78. When does the urine leakage occur with

a. coughing, sneezing, pushing, laughing, walking, with sport	yes	no
b. on getting up out of a chair, climbing stairs	yes	no
c. with bending/lifting	yes	no
d. on turning over in bed	yes	no
e. on getting out of bed	yes	no
f. with urgency	yes	no
g. around menstruation	yes	no
h. not applicable		

79. Do you have more leakage:

a. in the cold	yes	no
b. if a tap is running	yes	no
c. if you are nervous	yes	no
d. in the shower	yes	no

80. Does this restrict you in your work or leisure activities?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always

81. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to the sagging feeling **at this moment.**

No discomfort Much discomfort
l----------l
0 10

Domain Obstructive Micturition

82. Do you have the feeling after urinating that the bladder is completely empty?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

83. Do you have abdominal pain in the area of the bladder?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

84. Is urinating itself painful?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

85. When you have finished urinating and stand up, does it still dribble?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

86. How often have you been troubled with urinary tract infections?
    a. never
    b. only in the past
    c. < 1 time per year
    d. 1 time per year
    e. 1-2 times per year
    f. more than 2 times per year

87. Do you have any blood during urinating?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

88. Do you use incontinence pads to absorb the urine?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

89. How often must you change the pads?
    a. 1 time per day
    b. 2 times per day
    c. 3 times per day
    d. 4 times per day
    e. more than 4 times per day
    f. never

90. Do you use a catheter?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. daily
    f. not known

91. As a child, did you ever wet the bed?
    a. never
    b. till I was 10
    c. from 10 to 15
    d. >15

Quality of life

92. How badly are you restricted by your bladder problems at home, at work , and in your leisure activities?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

93. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regarding urinating **at this moment.**

No discomfort Much discomfort
l----------l
0 10

Domain Defecation Pattern

94. Do you feel a need to empty your bowels when you go to the toilet?

a. yes
b. no
c. sometimes

95. If so, when do you go to the toilet?

a. urgency
b. fixed time

96. Does something always come then?

a. yes
b. no
c. sometimes

97. How often on average per week do you have a bowel motion in the daytime?

a. 1 time per 2 week
b. 1 time per week
c. 3-4 times per week
d. 1-2 times per day
e. several times per day
f. other. Please indicate: _____

98. How often on average per week do you have a bowel movement at night?
    a. <1 time per week
    b. 1-2 times per week
    c. 3-7 times per week
    d. >7 times per week
    e. never
    f. other. Please indicate: _____

99. What is the consistency of the stool?
    a. thin, watery
    b. mushy
    c. soft
    d. hard
    e. varying consistency
    f. other. Please indicate: _____

100. Do you feel the stool coming out?
    a. no
    b. yes, sometimes
    c. yes, regularly
    d. yes, every time I move my bowels
    e. other. Please indicate: _____

101. Can you feel the difference between breaking wind and having a bowel movement?
    a. no
    b. yes, sometimes
    c. yes, regularly
    d. yes, always
    e. other. Please indicate _____

102. Do you have bright red bleeding during the bowel movement?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

Domain Fecal Incontinence

103. Do you ever have bowel incontinence?
    a. yes
    b. no

104. If so, how often does this occur?
    a. <1 time per month
    b. 1 time per month
    c. 1 time per 2 weeks
    d. less than 1 time per week
    e. 3-5 days per week
    f. always
    g. other. Please indicate: _____

105. Are you incontinent in the daytime or at night?
    a. only in the daytime
    b. only at night
    c. day and night

106. Can you put off the urge to empty your bowel for 15 minutes?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

107. Do you have bowel incontinence with

a. coughing, sneezing, pushing, laughing, walking, with sport	yes	no
b. on getting up out of a chair, climbing stairs	yes	no
c. with bending/lifting	yes	no
d. on turning over in bed	yes	no
e. on getting out of bed	yes	no
f. with urgency	yes	no
g. never		

108. Do you feel that faeces is leaking?
    a. yes
    b. no
    c. sometimes
    d. not applicable

109. Are your bowels ever incontinent without urgency?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

110. Does liquid ever leak out of the anus in the daytime?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

111. Have you ever had skin irritation around the anus?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

112. Have you ever had an itch around the anus?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

113. Can you hold in wind via the anus?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

114. Is there ever mucus in the stool?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

115. Do you use incontinence pads for leakage?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

116. How often must you change the pad?
   a. 1 time per day
   b. 2 times per day
   c. 3 times per day
   d. 4 times per day
   e. more than 4 times per day
   f. never

117. Do you take medicine to influence the stool?
   a. never
   b. seldom
   c. sometimes
   d. regularly
   e. always
   f. other. Please indicate: _____

118. Do you deliberately eat certain food to make the stool thicker or thinner?
   a. never
   b. seldom
   c. sometimes
   d. regularly
   e. always
   f. other. Please indicate: _____

Quality of life

119. How badly are you restricted by bowel incontinence at home, at your work or in leisure activities?
   a. never
   b. seldom
   c. sometimes
   d. regularly
   e. always
   f. other. Please indicate: _____

120. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to bowel incontinence **at this moment.**

No discomfort Much discomfort
l----------l
0 10

Domain Constipation

121. Whenever you go to the toilet to move your bowels do you need more than 15 minutes for this?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

122. Do you feel that the bowel is completely empty after the bowel movement?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

123. Do you feel that the stool is coming in pieces (several times consecutively)?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

124. Do you have to push hard to pass the stool?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

125. Do you ever have to use your hands to help the stool out?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

Quality of life

126. How badly does your constipation affect you at home, at your work or in leisure activities?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

127. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to bowel movement**s at this moment.**

No discomfort Much discomfort
l----------l
0 10

Domain Pelvic Floor Pain

128. Do you have pain around the anus after a bowel movement?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

129. Do you ever have abdominal pain during a bowel movement?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

130. Do you ever have cramp around the anus?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

131. Do you ever have pain in the area between the vagina and the anus?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

132. Do you ever have pain in the area around the tailbone?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

133. Do you ever have pain around the sit bones?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

134. Do you have pain during intercourse?	yes	no	
a. pain on penetration	yes	no	not applicable
b. pain deep inside	yes	no	not applicable

Quality of life

135. How badly are you restricted by your pain at home, at your work or in leisure activities?

a. never
b. seldom
c. sometimes
d. regularly
e. always
f. other. Please indicate: _____

136. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to the pain **at this moment.**

No discomfort Much discomfort
l----------l
0 10

Domain Sexual Dysfunction

137. Do you have
    a. intercourse?
    b. no intercourse?

138. Are the complaints mentioned earlier of influence during intercourse?
    a. yes
    b. no
    c. other. Please indicate _____

139. If so, which complaints?
    a. pain on penetration
    b. pain deep inside
    c. urine leakage during intercourse
    d. urine leakage during orgasm
    e. bowel incontinence during intercourse
    f. not applicable

140. Is there any relationship between getting a urinary tract infection and intercourse?
    yes no not applicable

141. Is sexual intercourse satisfactory for you?
    yes no not applicable

142. Is this due to the complaints mentioned earlier?
    yes no not applicable

143. Do you want professional help with your sexual problems?
    yes no not applicable

Quality of life

144. How badly are you restricted by your pain at home, at your work or in leisure activities?
    a. never
    b. seldom
    c. sometimes
    d. regularly
    e. always
    f. other. Please indicate: _____

145. Can you indicate below with a cross, on a scale of 0 to 10, how you are experiencing your complaints with regard to the pain **at this moment.**

No discomfort Much discomfort
l----------l
0 10

146. Have you had negative experiences in the past involving abuse or mistreatment?
yes no If no, stop here.

147. If so, did you have help for this? yes no

148. Have you been able to deal with this? yes no

149. If not, do you want help in dealing with it? yes no

APPENDIX IV: Confidential Participant Code Form: Patients

NAME: (First/Middle/Last)	**CODE:** (P, three digits)	**Test/Retest:** (yes or no)
e.g. Kelli M Berzuk	**P001**	**Yes**
	P001	
	P002	
	P003	
	P004	
	P005	
	P006	
	P007	
	P008	
	P009	
	P010	
	P011	
	P012	
	P013	
	P014	
	P015	
	P016	
	P017	

	P018	
	P019	
	P020	
	P021	
	P022	
	P023	
	P024	
	P025	
	P026	
	P027	
	P028	
	P029	
	P030	
	P031	
	P032	
	P033	
	P034	
	P035	
	P036	
	P037	
	P038	
	P039	

	P040	
	P041	
	P042	
	P043	
	P044	
	P045	
	P046	
	P047	
	P048	
	P049	
	P050	

APPENDIX V: Confidential Participant Code Form: Control Participants

NAME: (First/Middle/Last)	**CODE:** (C, three digits)
e.g. Kelli M Berzuk	**C001**
	C001
	C002
	C003
	C004
	C005
	C006
	C007
	C008
	C009
	C010
	C011
	C012
	C013
	C014
	C015
	C016
	C017

	C018
	C019
	C020
	C021
	C022
	C023
	C024
	C025
	C026
	C027
	C028
	C029
	C030
	C031
	C032
	C033
	C034
	C035
	C036
	C037
	C038
	C039

	C040
	C041
	C042
	C043
	C044
	C045
	C046
	C047
	C048
	C049
	C050

APPENDIX VI: Suggestions for Future Development of the PelFIs

Section or Domain	Content Validity (address ratings <3.00)	Test-Retest Reliability	Cronbach's Alpha	Lower-Value Items	Rephrase Items
Medical Intake	Omissions (2.375), Accuracy (2.500) and Relevance (2.875) of Questions				
Pelvic Organ Prolapse	Relevance (2.667) of Questions		Remove q54 Alpha=0.865	q54	
Micturition Pattern			Remove q63 Alpha=0.769	q61a, q61b, q61c, q63, q65, q66	q58 (separate 1-2 voids/night)
Urinary Incontinence		ICC=0.692 Not Significant	Remove q78d Alpha=0.883	q78d, q78e, 78g	
Obstructive Micturition			Remove q90 Alpha=0.740	q84, q85, q90, q91	
Defecation Pattern			Remove q95 Alpha=0.722	q94, q95, q96, q97, q102	q97 (further separate bowel movements/day
Fecal Incontinence			Remove q108 Alpha=0.866	q107a, q107b, q107c, q107d, q107e, q108, q118	
Constipation			Remove q127 Alpha=0.746		
Pelvic Floor Pain			Remove q136 Alpha=0.821	q128, q132, q134a	
Sexual Dysfunction	Omissions (2.571) and Relevance (2.857) of Questions		q137 Alpha=0.598	q138	
PelFIs (as a whole)	Accuracy (2.625) and Omissions (2.625) of Questions		Remove 9 items above	Remove 30 items above	Rephrase 2 items

Appendix VI summarizes areas that may be addressed in future to enhance the English-language PelFIs. The medical experts that assessed the content validity of the questionnaire indicated a need for improving omissions, accuracy and relevance of the items listed under the Medical Intake section of the document. For the domain Pelvic Organ Prolapse, experts indicated the need to improve the relevance of the questions. The also suggested the need to address the omission of necessary items within the domain Sexual Dysfunction while reviewing the relevance of some of the existing items of this section. Finally, experts noted a necessity for improved accuracy of questions and inclusion of necessary items throughout the whole PelFIs document.

The PelFIs questionnaire would benefit from evaluation of the domain Urinary Incontinence, to adjust items to improve the ICC value to a significant level and further support test-retest reliability.

Cronbach's alpha testing indicated a single question from each domain that could be removed to increase internal consistency of the corresponding domain, and nonparametric testing of each individual item on the questionnaire revealed 30 questions that did not reach significance and were therefore deemed relatively lower-value items. Many of the 9 Cronbach's alpha items also were noted to be low-value. In total, 33 items were identified for removal to create a minimum data set for a shorter-version PelFIs questionnaire.

Two items on the document, question 58 and question 97, were identified to benefit from rephrasing and adjusting the objective separation in answer selections. These adjustments were suggested for the benefit of better data collection as it would

make it easier for participants to answer the questions, and also for ease and accuracy in data analysis following collection.

APPENDIX VII: Informed Consent Form

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Validation of the English-Language Pelvic Floor Inventories Leiden (PelFIs) Administered Questionnaire.

Principal Investigator: Dr. Barbara Shay, University of Manitoba, R106-771 McDermot Avenue, Winnipeg, MB, R3E 0T6, 204.787.2756

Co-Investigator: Kelli Berzuk, 714 Medical Arts Building, 233 Kennedy Street, Winnipeg, MB, R3C 3J5, 204.982.9178

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study

This research study is being conducted to evaluate the validity and reliability of the female-version of the Pelvic Floor Inventories Leiden (PelFIs) questionnaire in the English language. This questionnaire has been proven valid and reliable in the Dutch language. More research is needed for pelvic floor problems to improve assessment and treatment options. For this, valid outcome measuring tools are needed. Validation to the English language PelFIs allows accessibility to clinicians on an international scale. This will encourage uniformity in patient assessment leading to higher quality of medical care to patients experiencing pelvic floor problems.

A total of 100 participants will participate in this study.

A. <u>Study procedures for ALL PATIENT participants:</u>

During the booking of your initial appointment at IPPC—Incontinence & Pelvic Pain Clinic, the receptionist asked if you would like to participate in this research study and we would like to thank you for agreeing to volunteer in this study.

Before beginning assessment or treatment, a qualified pelvic floor physiotherapist will ask you to answer each of the 149 questions on the PelFIs questionnaire and this will take approximately 20 to 30 minutes. As most of these questions would be routinely asked during your pelvic floor assessment, the completion of this questionnaire is beneficial to the research study but also necessary for a thorough evaluation of your medical history pertaining to pelvic floor problems. Information collected on the questionnaire may be used in your medical chart notes as well as in the medical report that will be sent to your primary care physician. The physiotherapist will record your answers to the questions asked. There will be a few questions that require you to record your feelings toward a symptom directly onto the questionnaire. Following the completion of the questionnaire your participation in the research study will be concluded and your physiotherapist will continue with your assessment and treatment. The pelvic floor physiotherapist administering your questionnaire may or may not be your treating pelvic floor physiotherapist, however your answers will be shared with the treating therapist to avoid repetition in patient history-taking.

<u>For those patient participants agreeing to complete the questionnaire 2-weeks or more prior to their scheduled appointment:</u>

When asked to participate in the research study, you agreed to complete the questionnaire on two separate occasions. For this sub-sample of volunteers, thank you for taking the time to present to the clinic a minimum of two weeks prior to your initial appointment with your pelvic floor physiotherapist. You will be asked to complete the 149-item questionnaire administered by a qualified pelvic floor physiotherapist and then again be asked the same questions by a different pelvic floor physiotherapist, at least two weeks later. Following the second administration of the questionnaire, you will have concluded your active involvement in the research study and assessment and treatment by your physiotherapist will begin.

B. <u>Study procedures for NON-PATIENT participants agreeing to volunteer in the control group:</u>

Thank you for agreeing to participate as a control in this research study. Your contribution benefits those individuals suffering from pelvic floor problems and works toward producing higher quality patient care in this field. Your volunteerism is sincerely appreciated. A qualified pelvic floor physiotherapist will ask you to answer each of the 149 questions on the PelFIs questionnaire and this will take approximately 20 to 30 minutes. Upon completion of this, your participation in the research study will be concluded. As many women are unaware that they are experiencing pelvic floor problems, if you have concerns or questions regarding your pelvic floor health after completing the questionnaire, please feel free to consult with the pelvic floor physiotherapist.

If you take part in this study, you will have the following procedures:

All participants will be asked to complete the 149-item questionnaire administered by the physiotherapist. Following the administration of this 20 to 30 minute questionnaire, your commitment to this research study will be complete.

For those patients agreeing to complete the questionnaire on two occasions a minimum of two weeks apart, following the second questionnaire your commitment to this research study will be concluded.

The researcher may decide to take you off this study if you are unable or unwilling to complete the 149-item questionnaire.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first.

<u>Risks and Discomforts for Patient Participants</u>

While there are no serious risks or physical dangers involved in this research study, we recognize that the questions are personal in nature and for some individuals it may be difficult to reveal your answers. Please be assured that your answers will be treated with the highest of respect at all times and personal privacy maintained. Your openness and fullness in answering the questions will be necessary for the highest quality in your treatment care.

Risks and Discomforts for Non-Patient Participants (Control Population)

While there are no serious risks or physical dangers involved in this research study, we recognize that the questions are personal in nature and for some individuals it may be difficult to reveal your answers. Please be assured that your answers will be treated with the highest of respect at all times and personal privacy maintained. Your honestly and willingness to divulge this information leads to improved research tools worldwide. Additionally, your responses may reveal pelvic floor problems that you have not been aware of experiencing. If this is the case please consult with your physician or the administering pelvic floor physiotherapist regarding any concerns. Recognizing pelvic floor problems may lead to quicker response in medical care if you so choose.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope the information learned from this study will benefit other people with pelvic floor problems in the future.

Costs

All the procedures, which will be performed as part of this study, are provided at no cost to you.

Payment for participation

You will receive no payment or reimbursement for any expenses related to taking part in this study.

For patient participants agreeing to attend and complete the questionnaire on two occasions, parking will be validated for the initial completion of the questionnaire. To thank you for volunteering your time solely for the benefit of research, please accept a copy of our educational book, I Laughed So Hard I Peed My Pants! A Woman's Essential Guide for Improved Bladder Control.

Alternatives

You do not have to participate in this study to receive treatment for your condition. Please talk to your pelvic floor physiotherapist if you prefer not to complete the questionnaire.

Confidentiality

For patients participants, your questionnaire becomes part of your physiotherapy chart. Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. You will note that your name is not included on the questionnaire but rather your information will be tracked by case number. All study-related documents will bear only your assigned study number. Questionnaires will be copied and processed for statistical analysis through the Biostatistics Department at the University of Manitoba. Data may be physically mailed as well as entered into the computer and transmitted electronically between sites. Again, to provide confidentiality no names will be placed on documentation.

The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will be collected on the questionnaire.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care at this centre. If the study staff feels that it is in your best interest to withdraw you from the study, we will remove you without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Medical Care for Injury Related to the Study

You are not waiving any of your legal rights by signing this consent form nor releasing the investigator(s) or the sponsor(s) from their legal and professional responsibilities.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions arise during or after the study contact the study physiotherapist: Kelli Berzuk at (204)982.9178 or the principal investigator, Dr. Barbara Shay at (204)787.2756.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Kelli Berzuk or her study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant signature_____Date _____

(day/month/year)

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given her consent

Printed Name: _____Date _____

(day/month/year)

Signature: _____

Role in the study: research co-investigator/research assistant

APPENDIX VIII: Content Validity Evaluation

Medical Intake Section (questions 1 through 50)

For this section, how **relevant** are the questions for ascertaining information on **medical background**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Pelvic Organ Prolapse (questions 51 through 56)

For this section, how **relevant** are the questions for ascertaining information on **pelvic organ prolapse**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Micturition Pattern (questions 57 through 70)

For this section, how **relevant** are the questions for ascertaining information on **micturition**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Urinary Incontinence (questions 71 through 78)

For this section, how **relevant** are the questions for ascertaining information on **urinary incontinence**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Obstructive Micturition (questions 79 through 90)

For this section, how **relevant** are the questions for ascertaining information on **obstructive micturition**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Defecation Pattern (questions 91 through 99)

For this section, how **relevant** are the questions for ascertaining information on **defecation**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Fecal Incontinence (questions 100 through 117)

For this section, how **relevant** are the questions for ascertaining information on **fecal incontinence**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Constipation (questions 118 through 124)

For this section, how **relevant** are the questions for ascertaining information on **constipation**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Pelvic Floor Pain (questions 125 through 133)

For this section, how **relevant** are the questions for ascertaining information on **pelvic floor pain**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

Domain Sexual Dysfunction (questions 134 through 139)

For this section, how **relevant** are the questions for ascertaining information on **sexual function**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions in this section.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate this section for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this section **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____

English-language PelFIs Questionnaire (Questions 1-139)

For the **complete questionnaire**, how **relevant** are the questions for ascertaining information on **pelvic floor dysfunction**?

0 Not relevant
1 Mildly relevant
2 Satisfactory
3 Very relevant
4 Perfectly relevant

Please rate the **accuracy** of the questions.

0 Numerous errors noted
1 Several errors noted
2 A few concerns with accuracy
3 A single area of concern with accuracy
4 No inaccuracies noted

Please rate the questionnaire for **omissions** of necessary questions.

0 Numerous omissions noted
1 Several omissions noted
2 A few concerns with omissions
3 A single concern of omission
4 No omissions noted, section fully complete

Please rate this research tool **overall**?

0 Numerous concerns
1 Several concerns
2 A few concerns
3 A single concern
4 No concerns

Comments: _____