

**DEEP AND SUPERFICIAL PELVIC FLOOR MUSCLE RESPONSES TO A
PAIN STIMULUS IN VESTIBULODYNIA**

by

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Abstract

Previous studies have suggested that protective responses in the pelvic floor muscles (PFMs), described in terms of hypertonicity and over-reactivity, are associated with and may worsen the symptoms of provoked vestibulodynia (PVD, i.e., chronic vulvar pain). A recent study reported that, upon manual palpation of the PFM, hypertonicity was consistently found in the superficial but not the deep PFM layers. The goals of this study were to compare superficial and deep PFM resting tone, protective response magnitude and onset timing to moderate perceived vulvar pain between women with and without PVD. Eleven women with PVD and eleven control women completed a gynecological examination and standardized PFM electromyography (EMG) testing. Three trials of surface EMG activity of the PFM were recorded while a pressure-pain stimulus (PPS) was applied to the vulvar vestibule. Increasing pressure was applied to achieve a perceived pain intensity rating of 6/10 using an 11-point numerical rating scale presented visually. The women with PVD had higher resting EMG activity in their superficial PFMs ($p=0.04$) as compared to the control group, while no difference was found at the level of the deep PFMs ($p=0.12$). Participants in both groups demonstrated contractile responses to the PPS in both the superficial and the deep PFM, and these responses were significantly higher ($p=0.0001$) in the superficial (50.06 vs 38.69 % maximal voluntary electrical activation [MVE]) as compared to the deep (24.88 vs 22.52 %MVE) PFM layers. Women with PVD had significantly higher PFM responses at the superficial layer as compared to the control women ($p<0.0005$). The onset of the superficial and deep EMG PFM responses followed the PPS application in both groups. No differences were found between the deep and superficial PFM onset latency to the timing of the PPS application. The results of this study suggest that women with PVD have

superficial PFMs that are more responsive to vulvar pain than those in non-affected women. The findings also suggest that superficial PFM over-reactivity, rather than deep PFM over-reactivity, is part of the PFM dysfunction reported in women with PVD.

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A handwritten signature in black ink, reading "Evélyne Gauthier". The signature is written in a cursive style with a large, stylized initial 'E'.

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List of Abbreviations

ANOVA	Analysis of variance
AP	Action potential
BC	Bulbocavernosus muscle
CBT	Cognitive-behavioral therapy
CI	Confidence interval
CMRR	Common-mode-rejection-ratio
EMG	Electromyography
H _a	Alternative hypothesis
ITT	Interpolated twitch technique
LA	Levator ani muscles
MVC	Maximum voluntary contraction
MVE	Maximum voluntary electrical activation
NRS	Numerical rating scale
PFM	Pelvic floor muscle
PFPT	Pelvic floor physiotherapy
PPS	Pressure-pain stimulus
PR	Puborectalis muscle
PT	Physiotherapy
PVD	Provoked vestibulodynia
RA	Research assistant
RMS	Root-mean-square
SD	Standard deviation
VAS	Visual Analog Scale

CHAPTER 1 INTRODUCTION

Provoked vestibulodynia (PVD), the most common form of chronic vulvar pain (i.e., vulvodinia), is present in approximately 12% of pre-menopausal women (Harlow & Stewart, 2003); however its pathophysiology remains unclear (Zolnoun, Hartmann, Lamvu, As-sanie, Maixner, & Steege, 2006). Women with PVD have been reported to have lower quality of life (Arnold, Bachmann, Rosen, Kelly, & Rhoads, 2006), lower sexual health (Arnold et al., 2006), higher anxiety (Stewart & Berger, 1997), more psychological distress (Meana, Binik, Khalifé, & Cohen, 1997), more frequent physical health problems (Danielsson, Torstensson, Brodda-Jansen, & Bohm-Starke, 2006), and more visits to health care professionals than non-affected women (Arnold et al., 2006; Metts, 1999).

Physiotherapists treat pain in order to restore normal movement patterns, and ultimately to restore normal function. That said, it is often impossible to tell whether movement dysfunction is a pre-existing condition, a causative factor or a protective response relative to the pain experience in patients with chronic pain conditions (Schneider, Palomba & Flor, 2004; Weijmar-Schultz, Basson, Binik, Eschenbach, Wesselman & Van Lankveld, 2005). In that vein, pelvic floor muscle (PFM) dysfunction is thought to be an important exacerbating factor in PVD, although it is not known whether PFM dysfunction is a causative or responsive factor in this condition. To date, the magnitude and timing of the PFM responses to provoked pain in women with PVD have not been tested objectively.

1.1 CHRONIC PAIN AND THE PFMS IN PVD

Researchers have suggested that skeletal muscles respond to pain, trauma, injury and negative emotions (Flor, Schugens, & Birbaumer, 1992). Muscle guarding in response to pain has been reported to be responsible for the ongoing experience of pain in patients with chronic low back pain (O'Sullivan, 2005), temporo-mandibular joint dysfunction (Schneider et al., 2004), chronic pelvic pain syndrome (Zermann, Ishigooka, Doggweiler, & Schmidt, 1999) and interstitial cystitis (Brookoff & Bennett, 2006). Maladaptive muscular strategies are thought to develop in response to acute pain, and if persistent, lead to more pain and eventually persistent chronic pain (Flor, Turk, & Birbaumer, 1985). Individuals with chronic pain have been found to have lower touch and pain thresholds at both the site of pain and remote sites, which are attributed to a state of sensitization of both the peripheral and central nervous systems (Moseley, 2003). This hypersensitivity has also been observed in women with PVD both at the vulvar vestibule (Granot, Friedman, Yarnitsky, Tamir, & Zimmer, 2004; Payne, Binik, Amsel, & Khalifé, 2005; Pukall et al., 2002; Pukall, Binik, & Khalifé, 2004), and outside the vulvar vestibule (Pukall et al., 2002). Recent research on the neurophysiology of pain has shown that hypervigilance and psychological stress increase this hypersensitivity to pain specifically in women with PVD (Payne et al., 2005). Women with PVD have been shown to have higher anxiety (Meana et al., 1997; Payne et al., 2005) and fear of pain (Payne, Binik, Pukall, Thaler, Amsel, & Khalifé, 2007) than non-affected women. Since voluntary PFM contractions (Seseke, Baudewig, Kallenberg, Ringert, Seseke, & Dechent, 2006) and stimulation of the vulvar vestibule (Pukall, Strigo, Binik, Amsel, Khalifé, & Bushnell, 2005) cause activation of brain regions associated with emotional

control (e.g., insular cortex, hypothalamus and cingulate gyrus), the author suggests that PFM dysfunction in PVD is perhaps triggered and/or worsened by the pain experience. The identification of muscular dysfunction and emotional facets of chronic pain conditions provides circumstantial evidence that the PFMs may be involved in the pathophysiology of PVD by way of persistent protective responses to vulvar pain caused by a state of hypersensitivity.

The hypothesis that the PFMs are involved in the pathophysiology of PVD is indirectly supported through evidence that treatments aimed at relaxing and retraining the PFMs are effective in decreasing pain and improving sexual function in women with PVD (Landry, Bergeron, Dupuis, & Desrochers, 2008a). Based on Travell and Simons' theories of myofascial pain syndrome (Simons & Travell, 1983; Simons & Mense, 1998) which suggest that a muscle affected by myofascial pain is highly excitable at rest, several researchers have used surface electromyography (EMG) recorded from the PFMs at rest to quantify PFM hypertonicity (i.e., elevated EMG resting activity and/or high resistance to passive stretch). Some authors have found hypertonicity of the PFMs in women with vulvar pain conditions (Glazer, Rodke, Swencionis, Hertz, & Young, 1995; Jantos, 2008; White, Jantos, & Glazer, 1997; Shafik & El-Sibai, 2002), while an equal number have failed to find any electromyographic evidence of hypertonicity (Engman, Lindehammar, & Wijma, 2004; McKay, Kaufman, Doctor, Berkova, Glazer, & Redko, 2001; Reissing, Binik, Khalifé, Cohen, & Amsel, 2004; van der Velde & Everaerd, 2001).

There are inconsistencies in the methodologies used in studies of PFM resting activity in women with PVD, which might explain the conflicting findings. First, subject

inclusion in many of these studies has been based on self-reported vulvar pain during intercourse, which is not specific to PVD; therefore, the samples in these studies might have included women with co-occurring vulvar pain conditions such as generalized vulvodynia or vaginismus (Glazer et al., 1995; Shafik & El-Sibai, 2002; van der Velde & Everaerd, 2001; White et al., 1997). Second, the studies by Glazer et al. (1995) and White et al. (1997) both used uncontrolled prospective (i.e., pre-post) designs. As such, their claims that hypertonicity of the PFMs is seen in women with PVD are not justified since normal tonicity of the PFM has never been described and case-control studies have not been reported. Third, the methodologies used for electromyographic data collection and analysis might have been a problem. Some researchers have failed to report their EMG amplitude (Reissing et al., 2004), and those who have reported their objective measures have failed to report the signal processing methods used or the limitations of their EMG system (Glazer et al., 1995; White et al., 1997). Furthermore, the current literature investigating the role of the PFMs in PVD describes studies that have assessed PFM EMG amplitudes at rest, during pain-free situations and/or during voluntary contractions, none of which is representative of the tasks during which women with PVD complain of pain. Indeed, primary muscular responses to painful stimulation are expected to be observed in the PFMs of women with PVD. A recent study by Reissing et al. (2005) reported that during intra-vaginal manual examination, over-reactivity of the PFMs is more common in women with PVD when compared to pain-free women. This phenomenon has not yet been studied using objective methods.

Research is needed to investigate whether the suspected PFM dysfunction in PVD is caused by PFM hypertonicity at rest and/or PFM protective over-reactivity. As such, the objectives of the current study were to test the former by investigating EMG activity at rest in women with PVD using a case-control design, and to test the latter by looking at PFM responses in women both with and without PVD during the application of a painful stimulus at the vulva. Using a standardized gynecological examination for all participants, the study protocol ensured that the findings were reflective of women with PVD specifically. This study was designed to provide a clear indication of the involvement of the PFMs during a representative painful situation in women with PVD.

1.2 DEEP AND SUPERFICIAL PFM LAYERS

There is evidence suggesting that the activation of the superficial and deep layers of the PFMs is distinct. According to DeLancey (2002), the superficial and deep PFM layers have different innervations, and display different contraction patterns. Devreese et al. (2007) have recently investigated the deep and superficial PFM layers separately using surface EMG electrodes and showed that, in most women, during voluntary PFM contractions the superficial PFMs contract before the deep PFMs. Their results suggest that in studies of PFM functioning, these muscle layers should be studied separately. Reissing et al. (2005) also reported that, on palpation of the PFMs in women with PVD, the superficial layer appeared to have more resting tone than the deeper one. The differences in reaction patterns across the two PFM layers have yet to be studied objectively in women with PVD. Such an investigation would provide insight into which muscle layer may be associated with

the pain in women with PVD and may have implications in physiotherapy (PT) treatment for women with PVD.

1.3 PURPOSE

The main purpose of this study was to determine if there are differences in PFM responses to painful stimulation of the vulvar vestibule (i.e., entrance of the vagina) between women with and without PVD, and whether the amplitude of the responses differ between muscle layers of the PFMs. In so doing, we also aimed to examine whether or not protective reactions occur before or after the occurrence of a painful stimulus.

1.4 RESEARCH QUESTIONS & HYPOTHESES

By measuring the resting activity and the PFM responses to a provocative test (i.e., a pressure-pain stimulus (PPS) applied at the vulvar vestibule), this research study addressed the following questions and tested the following alternative hypotheses (H_a) using an observational case-control design.

1. Does superficial and deep PFM EMG resting activity differ between women with PVD and pain-free women?

H_{a1} . It was expected that women with PVD would demonstrate higher EMG resting activity of the superficial PFMs, but not of the deep PFMs, than pain-free women.

2. Do superficial and deep PFM EMG peak response amplitudes to a PPS differ between layers and between women with PVD and pain-free women?

H_a2. It was expected that all women would demonstrate increases in EMG activity relative to resting EMG amplitudes at the deep and superficial PFMs in response to a PPS applied at the vulvar vestibule.

H_a3. It was expected that all women would demonstrate higher EMG response amplitudes of the superficial PFMs relative to the deeper PFMs.

H_a4. It was expected that women with PVD would demonstrate higher EMG response amplitudes at the superficial PFMs than pain-free women.

3. Do PFM pain responses precede or follow the PPS and how does this pattern compare between deep and superficial PFMs and between women with PVD and pain-free women?

H_a5. It was expected that the muscular reactions of the deep and superficial PFMs would occur before the PPS in women with PVD and as a reaction to the pain in pain-free women.

H_a6. It was expected that in all women, in response to the PPS, the superficial PFMs would contract before the deep PFMs, regardless of whether the deep PFMs responded before or after the PPS.

CHAPTER 2 LITERATURE REVIEW

2.1 PROVOKED VESTIBULODYNIA

The lifetime prevalence of dyspareunia (i.e., painful intercourse) may be as high as 60% in North American pre-menopausal women (Glatt, Zinner, & McCormack, 1990). One common cause of dyspareunia is Provoked Vestibulodynia (PVD; previously known as Vulvar Vestibulitis Syndrome), a subtype of vulvodynia (i.e., chronic vulvar pain) that affects an estimated 12% of pre-menopausal women (Harlow & Stewart, 2003). PVD is commonly described symptomatically as burning pain in response to pressure at the vulvar vestibule, which is located around the entrance of the vagina (Bergeron et al., 2001; Friedrich, 1987). Women with PVD often report more sexual dysfunction (e.g. 60% reported that PVD pain “quite a bit to extremely disabling” to their sex life [Arnold et al., 2006], reported 30% less intercourse attempts over a 6-month period when compared to pain-free women [Reissing et al., 2004], and had higher aversion towards sexual intercourse [Meana et al., 1997]), and an impaired quality of life relative to women not suffering from PVD (Arnold et al.2006). PVD has two subtypes: Primary PVD (i.e., the pain of PVD occurred upon first vaginal pressure/insertion) and secondary PVD (i.e., the pain of PVD occurred after a period of non-painful vaginal pressure/insertion).

Early diagnoses of PVD were made using Friedrich’s criteria (1987), which were based on: (a) severe pain on light vulvar vestibule palpation or attempted vaginal entry, (b) absence of other vulvar conditions, and (c) physical findings of vulvar erythema (i.e.,

redness at the vulvar vestibule; Moyal & Lynch, 2004). Erythema however, was later found to be an unreliable criterion in the diagnosis of PVD (Bergeron et al., 2001). Consequently, pain upon palpation in the absence of other vulvar pathology is the only criterion for a diagnosis of PVD. The most widely used gynecological diagnostic tool is the cotton-swab test and it remains the only available diagnostic test used for PVD in women who complain of dyspareunia (Haefner, 2000). The test consists of light pressure applied to multiple regions of the vulvar vestibule using a cotton-swab; a diagnosis of PVD is given if moderate to high levels of pain are reported during the test. Although the pathophysiology of this condition is still largely unknown, PVD is believed to be caused by several factors which may occur independently or in combination (Zolnoun et al., 2006). Suggested factors include central neuropathy as determined by a state of hypersensitivity during quantitative sensory testing (Bohm-Starke, Johannesson, Hilliges, Rylander, & Torebjork, 2004; Granot et al., 2004), peripheral neuropathy as determined by nerve ending proliferation (Bohm-Starke, Hilliges, Falconer, & Rylander, 1998; Bohm-Starke, Hilliges, Brodda-Jansen, Rylander, & Torebjörk, 2001), abnormal localized inflammatory responses (Perrigouard, Dreval, Cribier, & Lipsker, 2008) as determined by an increase in inflammation mediators that prevent the termination of inflammation (Babula, Linhares, Bongiovanni, Ledger, & Witkin, 2008), genetic factors as determined by the presence of alleles that prevent normal inflammatory processes (Gerber, Bongiovanni, Ledger, & Witkin, 2002) as well as ineffective antimicrobial immune system (Babula et al., 2008), vestibular mucosal tissue abnormalities as determined by an increase in vulvar vestibular blood flow (Bohm-Starke, 2001), repetitive vaginal infections (Mann, Kaufman, Brown, & Adam, 1992), and PFM

dysfunction as determined by hypertonicity (Engman et al., 2004; Goetsch, 2007; Reissing et al., 2005).

Despite agreement that PVD is multifactorial (Farage & Galask, 2005; Gunter, 2007; Landry, Bergeron, Dupuis, & Desrochers, 2008; Zolnoun et al., 2006), the different etiologies of PVD remain unclear. Figure 1 presents Zolnoun et al.'s (2006) unifying conceptual model of all suspected biopsychological causative factors of PVD.

There is currently an absence of objective physical findings associated with PVD. Also, in many cultures and in the medical community there are long-lasting taboos that surround discussion of women's sexual health (Farage & Galask, 2005). Due to these factors, many women fail to receive a diagnosis even after multiple consultations (Harlow, & Stewart, 2003), and are often told that they suffer from a psychological condition (Pukall et al., 2005). This misconception is further perpetuated by the fact that PVD is classified as a sexual dysfunction in the DSM-IV-TR (Diagnostic and Statistical Manual of Mental disorder 4th text revision, American Psychiatric Association, 2000) rather than as a pain disorder. In contrast, the International Society for the Study of Vulvovaginal Disease (ISSVD; Moyal-Barracco, & Lynch, 2004) considers PVD to be a chronic vulvar pain condition. Consequently, PVD is currently considered to be both a pain condition and a psychiatric condition, which causes much confusion as to where and how the treatment should be directed.

2.2 CHRONIC PAIN PATHOPHYSIOLOGY

The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”

The neurophysiology of chronic pain is complex and to this day poorly understood. However, a common assumption is that in acute pain, the brain assumes that the body is in danger and needs to respond in order to protect itself (Moseley, 2003). The body’s protective mechanism, mediated through the sympathetic nervous system and better known as the fight-or-flight response, increases muscle blood flow, muscle tone, respiratory rate, blood sugar and sensory acuity. When pain persists, this fight-or-flight response does not shut down, and the nervous system eventually responds more efficiently to both painful and non-painful stimuli, leading to hypersensitivity, neuropeptide release, muscle spasm and persistent pain. When this situation persists beyond the normal healing time, usually three to six months, and occurs in the absence of any other condition or disease, chronic pain is diagnosed (Moseley, 2003). As summarized by Gunter (2007): “An essential concept inherent to the IASP definition is that chronic pain is the disease process itself and does not need to be validated by a visible external cause, such as erythema or a lesion. Although there may be a triggering pathology, such as trauma or infection, the mechanisms that perpetuate the pain result primarily from changes to the nervous system [...]” (p.813).

A comprehensive review of all neurological changes in chronic pain is beyond the scope of this thesis, however, Moseley (2003) summarized that in chronic pain, changes in the peripheral and central nervous systems lead to a state of allodynia (i.e., pain response to

a non-noxious stimulus), and hypersensitivity or hyperalgesia (i.e., exaggerated pain response to a noxious stimulus). According to the same author, chronic pain eventually leads to increased brain activity in multiple pain-related cortical regions (e.g., anterior cingulate, insular and frontal cortices) in response to tactile and/or painful stimuli, a phenomenon called the “cortical pain neuromatrix”. One functional magnetic resonance imaging study showed that women with PVD demonstrate this cortical activation pattern, referred to as the “pain-signature”, when they experienced provoked vulvar pain (Pukall et al., 2005). Because PVD is a chronic recurrent pain, it has been argued that its pathophysiology differs slightly from other chronic pain syndromes, such that women with PVD present with an intact diffuse noxious-inhibitory control (DNIC; i.e., an endogenous analgesic system is turned on and pain thresholds are increased centrally when experiencing two simultaneous noxious stimuli; Johannesson, Nygren de Boussard, Jansen, & Bohm-Starke, 2006; Sutton, 2007). The presence of an intact DNIC response in women with PVD, despite its classification as a chronic pain condition, indicates that careful consideration must be made when making direct or indirect comparisons between PVD and other chronic pain conditions, as is typically done in the literature on PVD. Research on pain processing mechanisms in women with PVD is needed to determine PVD’s unique pathophysiology.

2.2.1 TREATMENT OPTIONS FOR WOMEN WITH PVD

Over the past decade, PVD has received much attention in the literature, with over 40 treatment studies published since 1996. A recent review of the treatment studies for PVD published between 1996 and 2006 identified four intervention categories: Surgical,

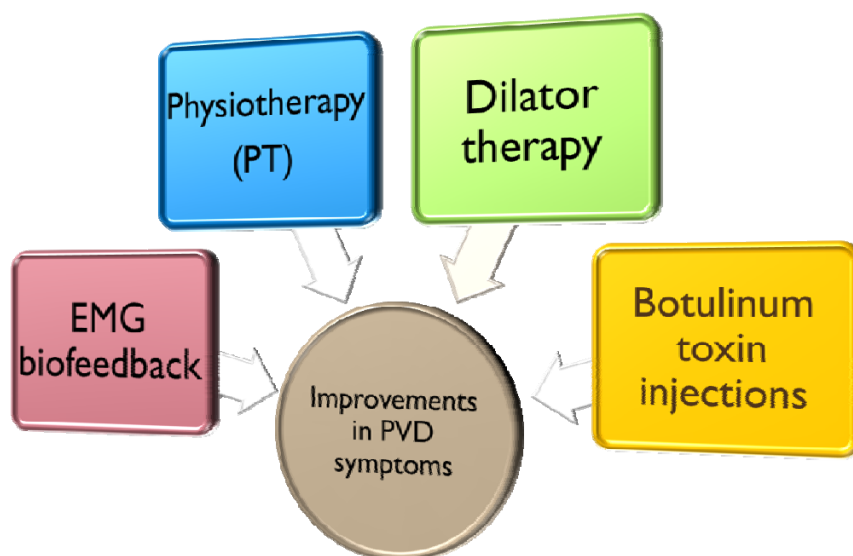
medical, behavioral/cognitive-behavioral therapy (CBT) and alternative treatments (Landry et al., 2008). Multiple interventions have been shown to be effective for PVD including EMG biofeedback (Glazer et al., 1995), surgery (Goldstein, Marinoff, & Haefner, 2005), pharmacological agents (e.g., amitriptyline anti-depressants, topical lidocaine, botulinum toxin A, and corticosteroid injections), dilator exercises (Murina, Bernorio, & Palmiotto, 2008), laser therapy (Leclair, Goetsch, Lee, & Jensen, 2007), hypnotherapy (Pukall, Kandyba, Amsel, Khalifé, & Binik, 2007), CBT (Bergeron et al., 2001), acupuncture (Danielsson, Sjoberg, & Ostman, 2001), and physiotherapy (Bergeron et al., 2002). Of all currently available treatment options, vestibulectomy surgery (i.e., removal of the posterior portion of the vulvar vestibule; Goldstein et al., 2006) is considered to be the most effective treatment, with reported pain improvement of 60-80% upon vaginal penetrative activities. However, CBT and biofeedback are the most promising conservative treatments in terms of pain reduction and sexual functioning improvements (Landry et al., 2008).

Despite the fact that there is currently no evidence that the PFMs play a causal role in PVD, several treatment approaches such as EMG biofeedback (Bergeron et al., 2001; Glazer et al., 1995; Danielsson et al., 2006; McKay, Kaufman, Doctor, Berkova, Glazer, & Redko, 2001), physiotherapy (PT; Bergeron et al., 2002), trans-cutaneous electro-stimulation (Napi, Ferdeghini, & Abbiati, 2003), dilator therapy (Idama & Pring, 2000), and botulinum toxin type A injections (Brown, Glazer, Vogt, Menkes, & Bachmann, 2006) have been developed whereby the PFMs are the main focus of treatment (Figure 1). CBT has been shown effective in improving PVD symptoms (Bergeron et al., 2001), and aims to reduce pain and improve sexual function through education and cognitive-behavioral psychology

with the assistance of a trained psychologist. CBT, however, also has a PFM component (e.g., home PFM exercises, dilation and relaxation). There thus seems to exist a strong common assumption that women with PVD present with hypertonicity of their PFMs, and that this hypertonicity is one of the key factors responsible for vulvar pain during intercourse (Glazer et al., 1995; Reissing et al., 2004; Reissing et al., 2005; Zolnoun et al., 2006).

As mentioned above, results from studies examining the effectiveness of interventions directed specifically towards rehabilitation of the PFMs (Bergeron et al., 2002; Danielsson et al., 2006; Glazer et al., 1995) have proven successful in reducing the vulvar pain associated with PVD in 52%-79% of women (Landry et al., 2008). In one randomized-controlled study on the effectiveness of three different interventions for PVD (vestibulectomy, CBT, biofeedback), women in a at-home biofeedback group (n=28) achieved a 35% reduction in pain ratings during intercourse; as compared to a 50% reduction achieved with surgery and a 37% reduction achieved with CBT (Bergeron et al., 2001). At two-and-one-half year follow-up (Bergeron, Khalifé, Glazer, & Binik, 2008), treatment gains in pain and sexual functioning were maintained across all treatment groups, and further improvements were seen in all three groups, suggesting that the women continued to benefit from the interventions over time.

Figure 1 PFMs-oriented evidence-based treatments for PVD



Despite the success of therapies targeted at PFM functioning, recent publications have highlighted a lack of evidence to support the involvement of the PFMs in PVD (Farage & Galask, 2005; Goetsch, 2007; Reissing et al., 2005; van der Velde & Everaerd, 2001; Weijmar-Schultz et al., 2005). Thus, studies investigating the true nature of the relationship between the PFMs and PVD are needed. Clinically, understanding the role of the PFMs in the etiology of PVD has strong implications for physiotherapy treatment (PT), since the focus of most PT treatment for PVD is the PFMs (Rosenbaum, 2005). Treatment predominantly aims to increase PFM flexibility, increase PFM voluntary control, and promote PFM relaxation, ultimately leading to an expected decrease pain, improved PFM and sexual functioning. Treatment goals are achieved through education, EMG biofeedback, PFM stimulation, the use of dilators, PFM home exercises, intra-vaginal manual stretching, desensitization of the vulvar vestibule using transverse frictions, as well as providing recommendations about

sexual function (Rosenbaum, 2005; Bergeron et al., 2002). Throughout this thesis, this battery of treatment protocols aimed at the PFMs will be referred to as pelvic floor PT (PFPT). Controlled studies are required to support the rationale underlying the PFPT approach by investigating the role the PFMs play in PVD.

2.3 PELVIC FLOOR MUSCLES

2.3.1 PFM ANATOMY

The PFMs (Figure 2) span from the pubic bone anteriorly to the coccyx posteriorly. They encompass numerous ligaments, muscles and fascial tissues, and can be described as a bowl supporting the abdominal organs. Based on its anatomical structure, the pelvic floor is traditionally referred to as having anterior, middle and posterior portions. The PFMs overlie each other such that they are separated into superficial, intermediate and deep muscle layers. There is a predominance of type 1 fibers in the deep PFMs, which suggests that their activity is predominantly tonic, whereas histologically, the superficial PFMs contain mostly fast twitch fibers, suggesting that their activity is predominantly phasic (Enck & Vodusek, 2006).

The superficial PFMs are composed of the ischiocavernosus muscle, bulbocavernosus (BC) muscle (also referred to as bulbospongiosus), the superficial transverse perineal muscle and the external anal sphincter. The latter has been suggested to share muscle fibers with the BC muscle (Shafik, Shafik, El-Sibai, & Shafik, 2007). The intermediate layer is comprised of only the deep transverse perineal muscle, and the deep layer contained the levator ani (LA; pubovaginalis muscle, puborectalis [PR] muscle,

pubococcygeus muscle, and iliococcygeus muscle) and the coccygeus muscle. The deep PFMs have been shown to play a role in continence (Thompson, O'Sullivan, Briffa, & Neumann, 2006; Wijma, Tinga, & Visser, 1991), while the superficial PFMs are said to have mostly a role in sexual functioning (Graber & Kline-Graber, 1979; Shafik et al., 2007). More details on the respective functions of the PFM layers are discussed in a later section.

The majority of the PFMs (i.e., the deep, intermediate and superficial layers) are innervated by the pudendal nerve, which arises from branches S2, S3, and S4 of the sacral plexus. However, the nerve supply to the PFMs has been the subject of controversy (Bharucha, 2006; DeLancey, 2005; DeLancey, 2002). It is believed that the PR and the external sphincter are innervated by separate nerves from the S2-4 nerve roots (Bharucha, 2006), and that the levator ani group is directly innervated by the sacral nerve roots S3-5 (Barber, Bremer, Thor, Dolber, Kuehl, & Coates, 2002). Delancey et al. (2002) suggested that the superficial PFM layer is innervated by a different branch from the pudendal nerve than the deep layer. Both deep and superficial PFM layers have also been suspected to have different activation patterns such that they contract in sequence rather than simultaneously (Enck & Vodusek, 2006). This hypothesis was supported by Devreese et al. (2007) who conducted an investigation on continent, perimenopausal women (n=32) looking at the voluntary contraction patterns of the deep and superficial PFMs layers. The authors found that almost all women recruited the superficial PFMs before the deep PFMs. The authors suggested that this onset-time difference (Median 21, inter-quartile range 20-21ms) in the typical lithotomy position (i.e., supine and knee-flexed) might be due to the cutaneous-anal reflex having a longer delay (60 ms) than the bulbocavernosus (BC) reflex that involves the

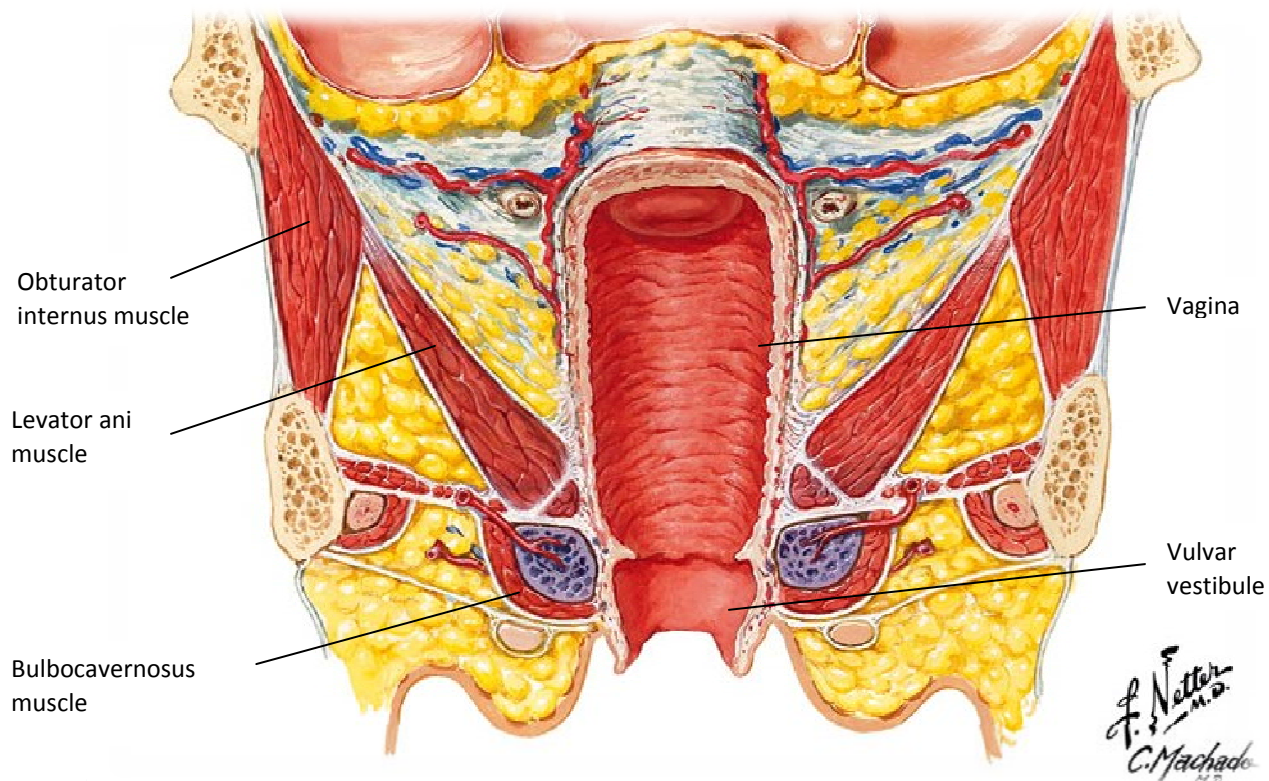
superficial PFMs (30 ms). They also suggested that the differences in predominant muscle fiber type might explain this difference in recruitment, whereby the slow-twitch deep PFMs respond later than the fast-twitch superficial PFMs (Devreese et al., 2007).

2.3.2 PFM FUNCTIONAL ANATOMY

In females, the functions of the PFMs are numerous. The PFMs work in collaboration with the diaphragm to facilitate the expiratory phase of breathing by increasing intra-abdominal pressure (Hodges, Sapsford, & Pengel, 2007). They co-contract with the abdominal and back musculature to enhance the stability to the pelvis and the spine (Hodges et al., 2007). They are also partially responsible for voluntary closure of the urethral, vaginal and anal openings and are thus essential to the maintenance of continence (Thompson et al., 2006; Wijma et al., 1991), and have been found to play a major role in sexual function in that they allow adequate sexual arousal and attainment of orgasm (Graber & Kline-graber, 1979). One study reported that the BC muscle shares muscular fibers with the external anal sphincter, and as such would assist in voluntary continence by assisting with increasing intra-vaginal pressure, which then further increases urethral pressure (Shafik, 1999; Shafik et al., 2007). The BC muscle also helps with sexual arousal through compressing the cavernous tissue of the vestibular bulb, pushing its blood to the corpora cavernosa, thus assisting in venous congestion (i.e., erection) of the clitoris (Shafik et al., 2007). The superficial PFMs are also suspected to be involved in vaginal closure by decreasing the size of the vaginal introitus (Shafik & El-Sibai, 2002), which might be part of a protective response towards unwanted vaginal penetration, or may assist in holding the penis inside the vagina during vaginal intercourse.

Figure 2 Ligamentous and fascial support of pelvic viscera

Notes: Frontal view of the PFMs. Deep and superficial muscle layers identified.
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There are multiple components to the proper functioning of the PFMs. These include connective tissue flexibility (i.e., tissue resistance to a passive vaginal stretch), tone (i.e., muscular resistance to a passive vaginal stretch), strength (i.e., the ability of the muscles to produce force during contraction), and motor control (i.e., the capacity to contract and relax voluntarily with appropriate timing to enhance synergistic functioning; Bø & Finckenhagen, 2001; Bø & Sherburn, 2005). Considering that relaxation of the superficial PFMs ensures proper and painless vaginal opening during vaginal penetration, these may be particularly

relevant in the presence of vulvar pain conditions. PFM functioning has typically been evaluated using surface EMG as well as visual and manual examination both in research and in clinical settings (Bø, Raastad, & Finckenhagen, 2005; Enck & Vodusek, 2006) .

2.3.3 PFM DYSFUNCTION

PFM tone dysfunction can be described as hypotonic or hypertonic and/or over-reactive. In women, the former is mostly associated with organ prolapse (Laycock, 1994) and incontinence (Schuessler & Baessler, 2003), while the latter is seen in cases of interstitial cystitis (Peters, Carrico, Kalinowski, Ibrahim, & Diokno, 2007), constipation, chronic pelvic pain (Gurel & Gurel, 1999), urethral syndrome (Bernstein, Philips, Linden, & Fenster, 1992), and sexual dysfunctions (Reissing et al., 2005; Rosenbaum, 2007a; Verit & Verit, 2007). Alterations in PFM tone are difficult to quantify and are therefore often described using subjective evaluation procedures. In a recent observational study (Goetsch, 2007) reported a 69% incidence of PFM hypertonicity in women with PVD (n=77/111). Hypertonicity was measured by digital intra-vaginal examination as conducted by a gynecologist, and was described as “tightness without tenderness and inability to relax [the PFMs]” (p.600).

Specific to women with PVD, and for the purposes of this study, over-reactivity is defined as a heightened muscular reaction to a stimulus in the presence of hypersensitivity to tactile stimulation at the vulvar vestibule and/or in the presence of fear of vaginal penetration (van der Velde & Everaerd, 2001; Simons & Mense, 1998). Hypertonicity differs from over-reactivity, and is described as a resistance to passive stretch in a relaxed muscle

(Reissing et al., 2005). Clarification is necessary since multiple terms have been used to describe hypertonicity and over-reactivity, which renders analysis of the literature confusing. According to the above definition, over-reactivity has been referred to as vaginal hypertonicity (Bergeron et al., 2001, Reissing et al., 2005), muscular instability (Glazer et al., 1995; 1998; White et al., 1997), hyper-irritability (McKay et al., 2001), a protective reaction (Murina et al., 2008; Reissing et al., 2004), spasm (Reissing et al., 2004), tension (Goetsch, 2007), hypertonus (Rosenbaum, 2005; Rosenbaum, 2007) vaginismus (i.e., a recurrent involuntary spasm of the outer third musculature of the vagina preventing vaginal penetration; van derVelde, & Everaerd, 2001, Reissing et al., 2004, Weijmar et al., 2005; American Psychiatric Association, 2000), and partial vaginismus (Engman et al., 2004). Vaginal spasm has never been documented quantitatively (Reissing et al., 2004), and consequently, vaginismus has recently been re-defined (Basson et al., 2004) as “a recurrent difficulty with vaginal penetration despite the women’s expressed desire to do so”. Vaginismus, PVD and dyspareunia often co-occur (de Kruiff, ter Kuile, Weijnenborg, & van Lankveld, 2000; Engman et al., 2004; Pukall et al., 2000), therefore the following literature review includes studies investigating women with vaginismus and dyspareunia complaints are also included.

2.3.4 EMG ASSESSMENT OF THE PFMS

Surface EMG is used to detect the electrical activity generated by active skeletal muscles during contraction, and is a representation of the action potential (AP) propagation that occurs along all muscle fibers involved in the contraction and that are within the pick-up area of the recording electrodes (DeLuca, 1997). The superimposition of APs creates the

observed EMG interference pattern and can be measured during voluntary or reflex muscle contractions (De Luca, 2006). Surface EMG is convenient for the study of PFM function as it is a relatively non-invasive method to measure muscle activity. It is commonly used in studies of PFM activity in women with incontinence (Bø & Sherburn, 2005) and vulvodynia (Glazer et al., 1998). Typically, to study the deep PFMs, electrodes are embedded on the sides of vaginal and/or rectal probes. Fine wire EMG is an alternative recording option, but is generally not feasible when studying vulvar pain, due to the heightened sensitivity of the perineal region (Raez, Hussain, & Mohd-Yasin, 2006). Needle EMG electrodes are used primarily to study motor unit morphological characteristics and firing properties (Enck & Vodusek, 2006), which is not generally appropriate when studying global muscle functions such as motor control, voluntary contractions, and reflex contractions (Raez et al., 2006).

2.3.5 SPECIAL CONSIDERATIONS WHEN USING EMG TO MEASURE PFM ACTIVITY

Interpretation of surface EMG signals should be made with caution. The most common problems associated with recording and analyzing surface EMG data include electrode placement variability (i.e, where the probe is seated in the vagina relative to the PFMs), crosstalk (i.e, detection by the EMG electrode of signals from nearby muscles that contaminates the EMG signal; De Luca, 1997), noise (i.e, detection by the EMG electrode of signals and/or frequencies coming from the environment and not the muscle itself; Turker, 1993), movement artifact (i.e., detection by the EMG electrode of noise caused by movement of the electrode with respect to the skin; Turker, 1993), and lack of normalization (Merletti, International Society of Electrophysiology and Kinesiology EMG Standards, 1999; Turker, 1993).

Electrode placement is very important since the further the electrodes are from the muscle belly, due to intervening tissue such as adipose or connective tissue, the smaller the EMG signal amplitude will be. Anatomical considerations should also be taken into account when positioning electrodes; in a differential recording, the electrode pair should not straddle the motor point of the muscle, rather, the electrodes should be positioned between the tendon insertion and the motor point, since both have proven to alter the characteristics of the EMG signal. This is difficult to achieve with the pelvic floor muscles, which are believed to have multiple motor points that are variable between subjects in terms of location (Enck & Vodusek, 2006) and are not easily detectable using traditional stimulation techniques (Basmajian & DeLuca, 1985).

Crosstalk can be reduced by positioning the electrodes far away from the edge of the muscle (De Luca, 1997). It is more difficult to avoid the muscle edges in small muscles, such as the pelvic floor muscles, where adjacent muscles (e.g., obturator internus) are closely associated with the muscle of interest, as opposed to in larger muscles (e.g., biceps brachii) which is remote from other muscles.

In order to minimize instrumental, environmental and crosstalk noise during EMG data recordings, bipolar recording (Soderberg & Knutson, 2000), grounding (Turker, 1993), small inter-electrode spacing (Turker, 1993), and short leads are recommended (Turker, 1993). These recommendations were followed throughout testing, and we respected a small inter-electrode recording surface and distance, which both further minimize noise (Turker, 1993). Motion artifact is another form of noise that can contaminate EMG recordings. Motion artifact appears in EMG data as large, low frequency potentials that result from

capacitance discharge. This may occur when EMG electrodes are moved across the skin or when electrode leads come into contact during a recording. The presence of motion artifact must be appraised visually by inspecting all data files, and the artifact must either be filtered or contaminated files must be removed.

Even when standardized recording electrode configurations are used, PFM EMG signal amplitudes vary tremendously across people, especially with between-day trials (Brown, 2008). As such, normalization techniques are often used in order to reduce between-subject and between-day variability. This is commonly achieved by dividing the EMG activity recorded during the task of interest to that recorded during a maximum voluntary contraction (MVC) effort. This normalization process allows investigators to report contraction amplitudes as a percentage of maximum voluntary electrical activation (%MVE), and ensures more reliable between-subject comparisons. Problems arise when normalizing PFM data to a MVC in that it is difficult to measure the consistency of the MVC using a force or pressure measure while simultaneously recording the MVE, since separate recording devices are used to measure EMG and pressure.

This problem is even further complicated when studying women with vulvodynia because inserting a measurement probe into the vagina might trigger a protective contractile response, which would increase resting electrical activity. In the data processing, resting activity is often removed from the EMG data to ensure that only the rise in EMG amplitude over its baseline level is counted as contractile activity. In using such a scheme to assess the MVE of the PFM, the resultant MVE might be biased to lower levels given that tonic activation of the PFM is always present to some extent. In this population, voluntary

muscle contraction might also be inhibited if the maneuver causes pain, lowering EMG amplitudes (Verbunt et al., 2005). Ideally, normalization of muscular contractions should be done using the interpolated twitch technique (ITT) which is believed to elicit a true maximum voluntary contraction by having the participant perform a voluntary contraction, then coupling it with an evoked nerve stimulation (Merton, 1954). The resulting contraction ensures a sound quantification of maximal muscle activity since all muscle fibers are activated. Again, in vulvodynia studies, the ITT is impractical, since it would require stimulation of the pudendal nerve while the participant is performing a voluntary PFM contraction with a vaginal probe in place to record EMG activity. There is no convenient access to pudendal nerve stimulation, and the invasiveness of such an approach would more than likely limit subject recruitment.

If appropriate measures are taken to minimize the impact of crosstalk, variability in electrode placement, and environmental noise and motion artifact, and if normalization procedures are carefully applied and cautiously interpreted, surface EMG can provide a valid and reliable measure of activity in the PFMs within a given day.

2.5 INVESTIGATION OF PFMS IN PVD USING EMG

To the authors' knowledge, Glazer et al. (1995) were the first to use surface EMG to study PFM activity in women with PVD. They introduced a model for the pathophysiology of PVD, suggesting that chronic pain in the vulvar vestibule could induce a state of hypertonicity within the PFMs, which in turn would perpetuate vulvar pain. Muscular hyper-excitability at rest in a sample of women with PVD was reflected in increased resting

muscular electrical activity as measured by surface EMG (Glazer et al., 1995). Thirty-three patients with PVD underwent an EMG evaluation of the PFMs using the “Glazer protocol”, which included, in sequence: (1) three 5-second recordings of PFM EMG with the muscles at rest, (2) six quick “flick” contractions, (3) three subsequent 5-second recordings of resting activity, (4) ten 10-second trials of alternating relaxation and contraction of the PFMs, (5) one 10-second recording of resting activity, and (6) one 60-second trial of a sub-maximal contraction. Participants were then provided with a portable biofeedback instrument, and were instructed to perform two daily biofeedback sessions of PFM exercises five days a week over a period of four months. Each session consisted of 20 minutes of alternating 10-second contraction followed by 10-second relaxation of their PFM. The treatment outcomes included measures of pain during intercourse on a visual analog scale (VAS), intercourse frequency, the standard deviation of the root mean square (RMS) amplitude of resting PFM EMG activity, contractile EMG RMS amplitude, and average rest EMG RMS amplitude (i.e., the standard deviation of the EMG signal during the five 10-second rest trials; a measure of PFM stability according to the authors). After PFM biofeedback training there was an 83% decrease in VAS pain intensity ratings during intercourse, a 68% decrease in resting EMG RMS amplitude, a 95% increase in contractile EMG RMS amplitude, and a 62% decrease in average rest EMG RMS amplitude. Twenty-two out of the 28 participants who initially were abstinent due to their pain had resumed intercourse by the end of treatment. According to Glazer (1995); “Rehabilitation [...] resulted in stronger more relaxed and more stable PFMs” (p.289), leading him to suggest that the women with PVD had initially presented with weak and “unstable” PFMs. This assumption, however, was not validated, since no control group

was included to compare baseline measures between women with and without PVD. Instead, comparisons were made only using pre- and post-treatment values. Therefore, changes observed in EMG amplitudes were most likely due to motor learning and/or muscle strength gains, and do not provide direct evidence that MVE amplitudes are lower in women with PVD than pain-free control women. The results of this study did indeed suggest that a treatment directed towards the PFMs (i.e., using EMG biofeedback during a PFM exercise protocol) may be effective in improving the symptoms of PVD. In particular, women regained their sexual functioning; perhaps the most important treatment outcome. However this result might have had more to do with the acclimatization to vaginal penetration using the vaginal probe, and less to do with changes in PFM strength and/or ability to relax. The equipment used by Glazer et al.(1995) for surface EMG recordings was an intra- vaginal probe (Thought Technology, model T6050) which was likely highly sensitive to crosstalk and noise interference (DeLuca, 2006) because they recorded monopolar signals from a large surface electrode area. It is not clear whether the electrode recorded EMG activity from the superficial, deep or both superficial and deep PFMs, and the authors did not report how they addressed limitations associated with motion artifact, noise or normalization.

A decade later, Engman et al. (2004) used a controlled experimental design and repeated the measurement protocol performed by Glazer et al. (1995) including an extensive physical examination as part of the evaluation of participants. Women with PVD underwent a gynecological examination to determine whether abnormal tone was present (i.e., resistance to a manual passive vaginal stretch). Hypertonicity was deemed present

when increased tone was found upon manual palpation of the relaxed PFMs, and/or when increased EMG activity (i.e., $> 2.0\mu\text{V}$; White et al., 1997) was observed at rest. Partial vaginismus was deemed present when a contraction of the PFMs partly closed the vagina during vaginal penetration activities, whereas total vaginismus was considered present when a severe contraction of the PFMs prevented vaginal penetration activities, as reported by the participants. The extent to which surface EMG of the PFMs could differentiate between 106 women with PVD and 27 asymptomatic women was then examined. Interestingly, of the 106 participants with PVD, all presented with some level of vaginismus during the intra-vaginal examination performed by the study gynecologist; however, no physical examination was performed on women in the control group, thus limiting the comparison between the incidence of vaginismus and hypertonicity in a pain-free population (Engman et al., 2004). Contrary to Glazer et al.'s (1995) theory, no differences in PFM mean RMS resting amplitude, mean RMS standard deviation, or mean RMS contractile amplitudes were found between the PVD and control groups when the Glazer protocol was performed. Despite subjective assessment of hypertonicity and over-reactivity in the PVD group, the EMG data did not support the presence of either hypertonicity or vaginismus in this population.

Reissing et al. (2004) conducted a study using EMG and a physical examination to compare PFM strength, endurance, resting activity, and tonicity of the deep PFMs in women with PVD (n=30), women with vaginismus (n=30), and pain-free women (n=30). Women were included in the vaginismus group if they had never been able to experience vaginal intercourse or had an inability to experience intercourse for over a year. Participants

underwent two gynecological examinations and one physiotherapy examination by health professionals who were blind to the participant's group status, followed by surface EMG measurements using a vaginal probe. Outcome measures included several questionnaires to rate pain during intercourse, PFM spasm as measured by perianal EMG sensors during insertion of the vaginal probe, EMG recordings of the deep PFMs during the Glazer protocol, PFM strength ratings using EMG amplitude during voluntary contraction and using a modified Oxford scale (0 = no contraction; 5 = strong contraction) with palpation, and tone ratings during digital palpation using a 7-point scale (-3 = very hypotonic; 0 = normal tone; +3 = very hypertonic). These scales are now widely used in clinical settings where PVD is assessed, especially in PT; however, their reliability as outcome measures has been questioned and sparsely studied (Frawley, Galea, Phillipps, Sherburn & Bø, 2006; Bø & Sherburn, 2005). Consistent with Engman et al.'s (2004) study, no differences in resting PFM EMG activity, as measured by an intra-vaginal or perianal probe, were found between the three groups. The authors also reported that women in the PVD group had lower PFM strength than women in the control group as demonstrated by surface EMG recordings; however, they did not present any data to support these results. This interpretation is particularly problematic since EMG amplitude is not a direct predictor of strength (Raez et al., 2006; DeLuca, 1997) and muscle activation in the women with PVD might have been inhibited due to pain generated by the probe used for measurement. Upon physical examination performed by the gynecologist, PFM spasm was reported in 86% of women with vaginismus, 93% of women with PVD, and 54% of pain-free women. The authors also screened for the presence of PFM spasm defined as an involuntary contraction of the PFMs

that prevents intra-vaginal examination or as an increase of 15 μ V (RMS) over the EMG resting activity during the Glazer protocol. None of the EMG data recorded from any of the groups supported the presence of muscle spasms.

Reissing et al. (2004), as in the Engman et al. (2004) and Glazer et al. (1995) studies, measured PFM reactivity using an intra-vaginal EMG probe which would have likely missed any response localized at the superficial PFMs. In addition, Reissing et al. (2004) did not provide information about how they quantified their EMG data, and therefore their results must be interpreted with caution. Interestingly, digital intra-vaginal examination by the physiotherapists suggested that there was higher tone in the superficial PFMs in the PVD group as compared to the control group. This difference was not observed across groups at the deeper layers of the PFMs. Since the EMG probe likely recorded predominantly from the deep PFMs, the superficial PFM responses present upon intra-vaginal palpation might have been missed.

In a later publication based on manual palpation findings of higher superficial PFM tone as compared to deep PFM tone, Reissing et al. (2005) suggested that superficial PFM hypertonicity may be a reaction to the pain felt in PVD rather than the cause of PVD. This suggestion is consistent with the hypothesis that had previously been put forward by Shafik & El-Sibai (2002) who examined the reactivity of the PFMs in women (n=7) with vaginismus as compared to control women (n=7) without vaginismus. In Shafik and El-Sibai's (2002) study, concentric needle EMG was used to record activity from the LA muscle, the puborectalis (PR) muscle, and the BC muscle. The PFM recordings were made while a vaginal dilator was introduced into the vagina. The researchers reported that women with

vaginismus had a higher resting EMG activity in all three muscles (muscle, mean \pm SD = LA, 149 \pm 43uV; PR, 154 \pm 48uV; BC, 150 \pm 43uV) when compared to pain-free women (LA, 97 \pm 28uV; PR, 86 \pm 27uV; BC, 81 \pm 23uV), which supports Glazer et al.'s (1995) hypothesis. During the dilator insertion, the authors found a greater increase in the BC muscle EMG amplitude than that found in the LA or PR, suggesting that perhaps the superficial layer of PFM is more involved in vaginismic reaction than deeper layers. Unfortunately, these results cannot be directly transferred to women with PVD since participants were recruited based only on subjective reports of a difficult vaginal penetration, and no gynecological work-up was done. Furthermore, as previously-mentioned in section 2.3.4, the dilator insertion could have generated motion artifact (i.e, apparent increases in EMG activity) that were not related to the presence of PFM hypertonicity and/or over-reactivity. Presumably motion artifact would be present to a larger extent in the superficial PFMs as compared to the deeper PFMs where more tissue motion had to occur in order to introduce the dilator into the vagina.

As previously mentioned, Reissing et al.'s EMG data, as well as those of Engman et al. (2004) and Glazer et al. (1995), were likely recorded only from the deep PFMs which might explain why all authors' subjective reports of hypertonicity and over-reactivity in the superficial PFMs were not confirmed by their EMG data. Selective assessment of the superficial PFMs might have revealed different results.

In comparison with EMG recordings of PFM tonicity, PFM EMG reaction amplitudes have only been reported in one study by van der Velde and Everaerd (2001), who compared the PFM EMG responses of women with vaginismus (n=45) and control women (n=32) to a

psychological stressor (i.e., a stressful film excerpts), and found no differences in EMG activation amplitude between the groups. Studies looking at PFM responses in the context of vulvar pain are lacking.

2.5.1 LIMITATIONS OF THE CURRENT RESEARCH ON PFM INVOLVEMENT IN PVD

As discussed in the previous section, the EMG studies published thus far have several major methodological limitations. All (Glazer et al., 1995, Reissing et al., 2004; van derVelde & Everaerd, 2001; Shafik & El-Sibai, 2002) but one study (Engman et al., 2004) contained incomplete description of the testing position and EMG equipment. Most studies also failed to report the details of their data recording and analysis technique (Glazer et al., 1995, Reissing et al., 2004; Shafik & El-Sibai, 2002). Moreover, the samples of women with PVD are not comparable since the criteria used to define women with PVD were inconsistent. Another seldom discussed major limitation across all studies is the issue of pain during the gynecological or EMG examination. It is possible that while attempting to evaluate PFM strength manually or with an EMG vaginal probe, researchers were causing vulvar pain or fear of such pain in their participants. Pain, fear and anxiety could have inhibited and/or limited the strength of their contractions.

As it stands, the lack of consistency in the classification of the populations studied, the use of questionable recording EMG equipment such as monopolar probes, and the absence of discussion of the data analysis and processing all lead one to question the evidence that there are differences in PFM contractility between women with PVD and pain-

free women. In addition, researchers have not yet established consistent and valid EMG protocols that differentiate between the deep and superficial PFMs in women with PVD.

2.6 SUMMARY

The relatively high success rate of therapies directed towards the treatment of the PFM has led investigators to evaluate and compare women with PVD to control women with respect to PFM strength, EMG resting activity, tone, control and endurance, expecting to see PFM dysfunction in women with PVD. There remains however no objective evidence that PFM strength, EMG resting activity, tone, control, strength, and endurance are altered in women with PVD.

Superficial PFM hypertonicity has been found to be present to some extent in women with PVD upon digital/manual palpation (Reissing et al., 2005), but EMG studies to date have not isolated the superficial relative to the deep PFMs. Overall, the literature supports the theory that hypertonicity and heightened PFM reaction may be associated with pain in women with PVD (Glazer et al, 1995; Shafik, & El-Sibai, 2002; Engman et al., 2004; Reissing et al., 2004; Reissing et al., 2005; Goetsch, 2007; Basson et al., 2004), yet no research has addressed the pain response of the PFMs using empirical data, nor has any assessed the PFM layers separately using EMG.

According to Zolnoun et al. (2006) the “development of rational treatment interventions informed by the underlying pathophysiology is critically impaired as a result of the lack of a conceptual model that examines the interplay between clinical variables [in women with PVD]” (p.400). The author wished to determine if PFM resting activity or over-

reactivity to painful tactile stimulation was present in women with PVD as compared to non-affected women, and if so, whether there was a preferential over-reactivity at the level of the superficial PFMs. A novel EMG approach to the evaluation of PFM functioning in PVD was developed such that superficial PFM (BC muscle) and deep PFM (LA muscle) responses to a pressure-pain stimulus (PPS) delivered to the vulvar vestibule were studied using surface EMG. The responses were compared between women with and without PVD in order to address a major research gap with respect to PFM dysfunction in his population, and in an attempt to better inform future practice in PFPT.

CHAPTER 3 METHODS

This study was conducted using an observational case-control design. Ethics approval was received from the Health Sciences Research Ethics Board of Queen's University (REB reference number: PSYC-070-07) before initiation of participant recruitment (Appendix A).

3.1 PARTICIPANTS

3.1.1 RECRUITMENT

Women previously diagnosed with provoked vestibulodynia (i.e., PVD group) and women without a history of vulvar pain (i.e., pain-free control group) who had participated in previous studies carried out at the Sexual Health Research Laboratory (SHRL) in the Department of Psychology, Queen's University, and who had given permission to be contacted about future studies were contacted and asked if they were interested in participating. Women in both groups were also recruited through advertisements posted throughout Queen's University campus and in the Kingston community. To target more specifically women in the PVD group, pamphlets and posters were additionally distributed to family physicians' and gynecologists' offices in Kingston, ON. (Appendix B).

3.1.2 CRITERIA

Interested women were considered for the study if they had consistently experienced vulvar pain during vaginal penetration for a minimum of 6 months and were

18 years of age or older. Women were excluded if they; a) had a major medical, psychiatric, or other pain condition that interfered with daily or sexual functioning (e.g., cardiac condition, incontinence, etc.), b) were taking medications that interfered with pain processing (e.g. anti-depressants), c) were parous, since delivery might have caused a change in the biomechanics of the PFMs caused by fascial tears, nerve damage, etc. (Dietz & Wilson, 2005), d) had previously had genital surgery, since the integrity of the tissue might have been altered, thus altering pain perception in the vulvar vestibule, e) were peri- or post-menopausal, considering that hormonal changes influence the quality of the skin, cause dryness, atrophy, and fragility (Hall & Philips, 2005) which might in turn modify the pain experience, f) had a pacemaker, since they would later take part in a protocol that included intra-vaginal transcutaneous electrical nerve stimulation for which treatment of a patient with a pacemakers is contraindicated.

Thirty women with vulvar pain complaints were screened by a research assistant (RA) for eligibility over the phone (Appendix C). After screening, nine women were ineligible to participate, and two were not interested in the study. Reasons for ineligibility were: postmenopausal status (n=4), absence of chronic vulvar pain (n=4) and incontinence (n=1). Having to exclude only one woman due to incontinence was not surprising: Women with genital pain are less likely than controls to have had a pregnancy (61% vs. 92%; Arnold et al., 2006) and the age of pain onset is typically before 30 years-old (57%-75%; Harlow & Stewart, 2005; Harlow, Wise, & Stewart, 2001). Women with PVD in the current study also had a low BMI (mean $22 \pm SD 2$). A high BMI, a prolonged labor and older age are all risk factors for developing incontinence (Chiarelli, Brown, McElduff, 1999). Women who took

part in this study did not meet any of the risk factors for incontinence. The remaining 19 women met the eligibility criteria and were sent a copy of the letter of information and consent form for their review (Appendix D). Participants had the opportunity to contact the investigator with any questions they had to ensure that they had made an informed decision to participate in the study. All 19 women underwent the gynecological examination, which confirmed the presence of PVD and the absence of other conditions (i.e., vaginismus, vulvar dermatitis, yeast infections, and urinary tract infections) in all but one woman who was diagnosed primarily with vaginismus, and she was thus excluded from the study. Women who presented with deep pelvic pain (n=4) in addition to their PVD pain were considered for the study. Eighteen women were thus asked to participate in the study; two declined to participate, one became ineligible when she started taking daily analgesics for migraines, and one was found ineligible on the basis of her anxiety disorder that interfered greatly with her daily functioning. All remaining 14 participants completed the protocol between October, 2007 and February, 2008, with the exception of one who move out of town before the end of her treatment. Upon completion of the testing, data from three women with PVD were not included in the analysis due to EMG equipment failure during testing, which meant that 11 women with PVD were included in this study.

A total of 20 non-affected women were screened for eligibility for the control group by a RA as well. Reasons for ineligibility were: having never had a previous gynecological examination (n=1), taking medication for depression (n=1), and an impossibility to undergo the gynecological examination due to scheduling conflict (n=3). After screening, 15 women were booked for the same standardized gynecological examination to ensure that they met

the inclusion criteria for the control group. They were emailed a copy of the letter of information and consent form for their review. Upon completion of the gynecological examination, all women were considered eligible for the study, and were booked in for the pelvic floor testing. Four women later cancelled their appointment and participation with no justification. Thus, 11 pain-free women completed the testing between November, 2007 and April, 2008.

3.2 PROCEDURES

Participants who met the study criteria participated in one 30-minute gynecological examination with the study gynecologist, and one 90-minute pelvic-floor testing session conducted by the physiotherapist graduate student investigator in the Pelvic Floor Laboratory at the School of Rehabilitation Therapy, Queen's University. During all testing sessions, an RA was present to assist with testing. Women in the PVD group subsequently entered into a separate treatment study.

3.2.1 GYNECOLOGICAL EXAMINATION

Women met with an RA at the Department of Obstetrics and Gynecology at Kingston General Hospital before the gynecological examination and reviewed and signed the consent (Appendix D) and confidentiality forms (Appendix E) which included information on the subsequent treatment study. Women considered for the pain-free group thus completed a different consent form (Appendix D). A short medical history was taken before they entered the examination room. Women were accompanied by the RA in the examination room and introduced to the obstetrician and gynecologist who conducted all

gynecological examinations in this study. Women were then asked to undress from the waist down and assume a lithotomy position on the gynecological table and were left alone in a private area to do so. The gynecologist then examined the internal and external genitalia and performed the cotton-swab test (i.e., a standard medical diagnostic test for PVD, which consists of 19 palpations of the labia majora, labia minora and the vulvar vestibule in a randomized order). For each of the 19 sites, women were asked to rate their pain intensity on a scale of 0 (no pain at all) to 10 (worst pain ever felt). The diagnosis of PVD was made by an obstetrician/gynecologist based on the participants' self-report of pain and higher than average pain ratings (i.e, above 4/10 on an 11-point numerical pain intensity scale [NRS] presented visually) on the cotton-swab test. Women were informed if they were eligible for the study immediately after the examination. If ineligible, they were provided with an information package on vulvar pain including a list of available resources in the Kingston area. An appointment for the pelvic-floor muscle testing session was made with eligible participants immediately after completion of the gynecological examination.

3.2.2 PFMS TESTING SESSION

Each woman met with the RA and with the investigator at the Pelvic Floor Laboratory in the School of Rehabilitation Therapy at Queen's University. The investigator, the RA and the women introduced themselves and reviewed the testing protocol that had been explained in the consent form. Women were informed that they could withdraw from testing at anytime without any negative consequences. Questions and concerns raised by the woman were addressed immediately. Each woman was then asked to provide a comprehensive subjective report of her past and current medical conditions, and

demographic information (e.g., age, height, weight, race, occupation, medical history, smoking history, and menstruation history) to be used later to compare the two groups.

3.2.2.1 VISUAL INSPECTION OF THE PFMS

Each woman was instructed to undress from the waist down, put on a gown, and get into a half-sitting lithotomy testing position, which consists of the regular gynecological position with feet supported in footrests, knees in approximately 60° of flexion, hips in 80° of flexion (where hip flexion = 0°-140°, hip extension = 0°-45°), and back supported with pillows. She was left alone in a curtained area to do so. When gowned and in the testing position, the woman indicated to the investigator and the RA that she was ready to begin.

A strap was placed around the woman's thighs to support her legs and to prevent external rotation, or contraction of the internal rotators and/or adductors of the hip which might have caused crosstalk and/or fatigue during testing. Efforts were made to make the participant as comfortable as possible using pillows and towels as necessary. In the event that a participant did not relax her legs and/or her buttocks while in the testing position, the investigator provided tactile and verbal feedback to encourage relaxation. When the participant felt ready to do so, she lifted the gown herself to indicate that she was ready to start testing. The pelvic floor visual inspection was performed to ensure normal voluntary and reflex functioning of the PFMs by asking the participant to cough twice, then to contract her PFMs twice. The expected outcome in both instances was an upward movement of the perineum (i.e. the region between the vaginal entrance and the anus), without any compensatory movements of the pelvis, hip, or abdominal musculature. Each woman demonstrated the appropriate PFM reflex response upon the cough screening, which

suggested the absence of a neurological condition. Additionally, all women were able to voluntarily contract their PFMs, but some need to be cued on how to isolate the PFMs and to avoid co-contraction and/or compensations of the adductors and/or buttocks.

3.2.2.2 EMG SET-UP

The EMG electrodes were positioned over the superficial PFMs using two disposable self-adhesive EKG AgAg-Cl surface electrodes (Harris Healthcare, Falls Church, VA) placed in a differential configuration on each side, over the right and left BC muscles. The surface EMG electrodes were custom modified to measure 0.8 cm x 0.8 cm, and edges were rounded for comfort. The inter-electrode spacing from center-to-center was 1.0 cm. This region of electrode placement is usually hairless in women, and corresponds to the space between the labia majora and the labia minora. Before the electrodes were positioned, the participants performed a PFM contraction and the BC muscles were palpated in an effort to account for anatomical variations and to situate the electrodes over the muscle belly (Appendix F). As discussed in section 2.3.5, appropriate electrode placement is essential to limit contamination of the EMG signal by crosstalk from surrounding muscles.

Next, the investigator assisted each woman to insert their single-use vaginal Femiscan™ probe (Mega Electronics Ltd, Kupio, Finland; Appendix G) into the vagina. Assistance was provided due to the complexity of the set-up, and to minimize discomfort during the insertion of the probe. The end of each probe was lightly coated with a non-conductive water-based gel lubricant (K•Y® Brand-marque, Gel™/MC). Each probe had two pairs of bipolar longitudinal stainless steel EMG electrodes 45 mm in length and 3 mm in

width mounted on either side of a plastic frame to record from the deep PFMs (LA muscle group). During the insertion, the investigator asked the participant to alternately contract, then relax her PFMs. The probe was advanced after the relaxation in order to minimize discomfort. In no instance did the vaginal probe insertion cause too much discomfort to prevent its use. A self-adhesive EKG AgAg-Cl external reference surface electrode (Harris Healthcare, Falls Church, VA) was used for both the deep and superficial channels and was placed over the left anterior iliac spine. Throughout the entire testing session women were instructed to hold the probe straight and in place using their right hand to minimize electrode displacement with respect to the PFMs.

3.2.2.3 PPS EQUIPMENT

Five vulvalgesiometers were used to standardize the PPS throughout the experiment. These devices are comprised of a cotton-swab attached to a loaded spring which delivers standardized pressures (Pukall et al., 2004; Pukall et al., 2007; Appendix H). Pressures are expressed in grams and are calculated over an approximate area of 0.4 cm². Before initiation of the testing, an explanation and demonstration of one of the vulvalgesiometers was performed on the woman's thigh to familiarize her with the tool. The cotton-swabs were lightly coated with a water-based lubricant (K•Y® Brand-marque, Gel ^{TM/MC}) to prevent skin irritation, and although some of the pressures were uncomfortable or painful, they were not sufficient to damage the skin. Women were informed that they could withdraw from any stimulus that was uncomfortable at any time, while bearing in mind that any pain induced by the vulvalgesiometers was to be felt for a transient time of one second in average.

3.2.2.4 EMG TESTING

Surface EMG data were sampled at 1000 Hz from all recording sites (i.e., deep and superficial PFM) bilaterally. All EMG data were amplified using Delsys Bagnoli-8 EMG system amplifiers (gain 1000, bandpass filter 20-450 Hz, CMRR > 100 db at 60 Hz, input impedance > 100 MOhms). All EMG channels were interfaced with a 16-bit National Instruments analog to digital converter (PCI-MIO-16XE-10). Data were acquired and stored on a Pentium III personal computer using EMG Works Acquisition™ software.

The woman was first instructed to relax and remain still while PFM resting activity was recorded over a 10-second period. Next, a 10-second test recording of PFM voluntary contraction data were acquired in order to verify adequate functioning of all EMG channels. Then, each woman was asked to contract her PFM as strongly as possible (i.e., MVC) over 5 seconds despite the fact that she might feel a slight discomfort caused by the vaginal probe. EMG data from all channels were recorded during this test, and were used as the MVC (MVE once processed) for normalization purposes.

The woman was then made aware that at some point during each of the next series of 10-second EMG recordings, a pressure would be applied at her vulvar vestibule using the vulvalgesiometers, and she was cued before the initiation of each recording. During each 10-second trial, a different pressure was applied at the 6 o'clock location on the vulvar vestibule. Women were told to relax while the PPS was applied, and they were asked to indicate whether they felt a touch or a pain sensation using the following grading system; no feeling of touch or pain (N), touch (T), or pain (P). They were also instructed to rate their pain on an 11-point NRS presented visually of 0 (no pain) to 10 (worst pain ever felt). An

inter-stimulus interval of 20 to 30 seconds between trials was respected throughout the testing. The pressures were applied using vulvalgesiometers, beginning with 10 g and they were then increased in the following order: 25, 60, 80, 150, 200, 300, 400, 500, 650, 800, 950 g. When pain intensity ratings reached 6 out of 10, the pressure was not increased any further as that pressure level was deemed the PPS for that participant. At this point, two additional trials were conducted using the pressure that resulted in the 6/10 pain and pain intensity ratings were recorded. These three trials marked the end of the response testing. All women reached a pain of 6 out of 10. The same pressure was used on the second and third trials for that subject, but the perceived pain may have differed. For example, the perceived pain during the second trial might have been 4/10 and the perceived pain on the third trial might have been 8/10. As such, pain ratings of 6/10 were not recorded consistently in all women for all three trials, despite standardizing the PPS intensity.

Two blank trials (i.e., no-stimulus) were included during the testing during which no pressure was applied to the vestibule, and participants were warned before the fact not to expect any contact at the vulva. During the first blank trial, only positioning of the vulvalgesiometer close to the vulvar vestibule occurred. During the second blank trial, a pressure of 10 g was applied at the perineum. These two blank trials were performed to determine if movement artifact was a problem when positioning or applying pressure with the vulvalgesiometer when no response was expected, and to determine whether there was any motion or other artifact that might have influenced the response timing and amplitude analysis. The data from these blank trials were inspected visually for such noise, and did not show any motion artifact or noise (Appendix I). The absence of motion artifact upon the two

blank trials reinforced the thought that the set-up was appropriate and that noise was not a major issue in the current experiment.

3.2.2.5 CONCLUSION OF THE TESTING SESSION

The investigator assisted the participant in removing the probe and the EMG electrodes. The participant was then left alone in the private area to change back into her regular clothes. Any questions and/or concerns were addressed, and an information package on PFM function, PVD and treatment options was provided to women in both groups. Only the women in the control group were given a debriefing sheet (Appendix J), considering that all women with PVD were to enter a treatment study, and would be provided with a comprehensive debriefing sheet upon completion of that study.

3.3 DATA PROCESSING AND ANALYSIS

All raw EMG data (e.g., resting activity, blank trials, maximal voluntary contraction [MVC] and responses to the PPS) were plotted in EMG Works Analysis and inspected to ensure they were free from noise, including motion artifact. When inspected visually, files that had excessive noise and apparent artifact were not included in the analysis. The raw EMG data were filtered and smoothed by computing the RMS amplitudes using a 100ms moving window, with 99ms overlap across each data file. The RMS of the resting activity was removed from each MVC and response trial using the lowest RMS of the pre-PPS resting activity within each trial. Mean RMS resting activity was computed over 8 seconds of the 10-second rest trial for each channel and was used for the analysis of resting activity between muscles and groups.

In testing alternative hypotheses (H_a) 1, 2, 3 and 4 for each muscle layer and each muscle side of the PFMs, peak EMG amplitudes were determined as the highest RMS value achieved within a window of 3-seconds after the PPS application in each of the three trials per subject. Raw (i.e., referring to non-normalized and RMS smoothed data) and normalized data (%MVE) were analyzed. The data were normalized as shown in Table 1.

Table 1 EMG data normalization process

Notes: PFM = pelvic floor muscle RMS = root-mean-square MVE = maximal voluntary electrical stimulation MVC maximal voluntary contraction PPS = pressure-pain stimulus

Variables	Normalization equation
<p>i = Trial number (e.g., 1,2, and 3)</p> <p>j = PFM site (e.g., superficial right, superficial left, deep right, and deep left)</p> <p>Max RMS_{i,j} = Peak RMS response 3s post PPS of trial i of muscle j</p> <p>MVE_j = Maximum voluntary electrical activation defined as the peak RMS of muscle j recorded during MVC trial</p>	$\%MVE_{ij} = \frac{Max\ RMS_{ij}}{MVE_j} \times 100$

In testing H_a 5 and 6, each PFM response onset times (i.e., latencies) were determined visually as the time at which the RMS smoothed EMG rose consistently (i.e., did not drop again until after the response) above the peak of the smoothed EMG resting activity and were expressed in seconds. Onset times from the right and left sides of the

PFMs were averaged in both the superficial and the deep PFMs. The onset time at which the PPS was delivered, as indicated by the footswitch activation, was then subtracted from the relative PFMs' onset times.

3.4 STATISTICAL ANALYSIS

Normality tests for the distribution of each data set were performed. Levene's tests were used to ensure equal variances between strata (e.g. group, muscle layer, and muscle side). The significance level for all tests was set at an alpha of 0.05.

Right and left sided differences in PFM activation were tested for each group and muscle layers. Since there were no significant group by muscle layer by muscle side interactions, and no group by muscle side or muscle layer by muscle side interactions and no muscle side main effect were found, data from the two sides of the PFMs were collapsed.

Alternative hypotheses (H_a) 2, 3 and 4 were tested using both the raw EMG and normalized EMG. For reasons discussed in section 4.4, the raw superficial and deep PFM EMG amplitudes were analyzed separately between the different groups. Values were reported as mean \pm SD and plotted using interval plots with a confidence interval (CI) of 95%. For H_a 1 and 2, one-way analyses of variances (ANOVAs) were performed for the deep and superficial PFM layer data to compare resting EMG amplitudes and raw MVE EMG peak amplitudes between the groups (pain-free/PVD). A type 3 two-way ANOVA, using a general linear model, was performed for normalized EMG peak response amplitudes to test for difference between group (pain-free/PVD) and muscle layer (superficial/deep). The

interaction between group and muscle layer was included in the model. Tukey's post-hoc analyses were performed to investigate significant interactions where applicable.

Alternative hypotheses (H_a) 5 and 6 were tested using the onset time of the PFM relative to the onset time of the PPS application time (i.e., latency). Onset times were compared between groups and muscle layers using a two-way ANOVA. The interaction between group and muscle layer was included in the model. Right and left sides were combined for both muscle layers. Data were graphed using interval plots for visual inspection, and it was determined that if the 95% CI for onset time included zero, the muscle response was considered to have occurred simultaneously with the stimulus. If the onset time was lower than zero, the responses were considered to have occurred in anticipation of the stimulus, and if it was greater than zero, the response was considered to have occurred in response to the stimulus.

CHAPTER 4 RESULTS

4.1 PARTICIPANTS

Eleven women with PVD and eleven pain-free women met the inclusion criteria, participated in the study and had usable EMG data. All participants completed the gynecological examination before the testing with the exception of two women, who performed it within one month after testing, due to scheduling issues. Testing was performed between November 2007 and June 2008. The groups did not differ in terms of BMI, hormonal contraceptive use, and age (Table 2). Testing in the PVD group was performed at 11:30 am (\pm SD 3 hours) and in the pain-free group it was performed at 12:00 pm (\pm SD 3 hours). There was no difference in the time of day of testing (T-value=-0.21, $p=0.84$) between the groups. There also was no difference between groups in terms of the point of their menstrual cycle (PVD group= Mean 15 \pm SD 7 days; Pain-free= Mean 20 \pm SD 8 days; T-value=-1.39, $p=0.18$) at which testing was performed. The pain ratings during the testing are shown in Table 3. The demographic information is shown in Table 4.

4.2 DATA EXCLUSION

All EMG data were plotted using EMG Works Analysis and visually inspected for any inconsistencies (see Figure 3 for sample raw EMG data). Data files were excluded using the predetermined criteria outlined in Chapter 3. The number of excluded response data files varied between groups: PFM responses (PVD group N=3/132 (4 muscles sites*3 trials*11 women), pain-free group N=0/132) and PFM onset time (PVD group N=11/33 (3 trials*11

women), pain-free group=13/33). For more details and for examples of the excluded data files, see Appendix K.

Table 2 Participants' demographic information

Notes: PVD = Provoked Vestibulodynia BMI = body mass index M = Mean SD = standard deviation NRS = Numerical rating scale (0 to 10 pain intensity scale) * represent significant difference between groups at $p \leq 0.05$

Participants' characteristics	PVD group	Pain-free group	t-test
	M ± SD	M ± SD	p-values
<i>General</i>			
Age (years)	22 ± 2	21 ± 1	0.06
BMI (kg/m ²)	22 ± 2	22 ± 2	0.84
Age of first menstruation (years)	12 ± 2	13 ± 1	0.21
Duration of PVD (years)	4 ± 2	-	-
Worst PVD pain	9 ± 2	-	-
<i>Menstrual cycle</i>			
Average menstrual pain (NRS)	4 ± 3	1 ± 2	* 0.03
Worst menstrual pain (NRS)	7 ± 3	2 ± 3	*0.001

Table 3 Participants' pain levels during testing

Notes: PVD = Provoked vestibulodynia M = Mean SD = standard deviation MVC maximum voluntary contraction NRS= Numerical rating scale (0 to 10 pain intensity scale) * represent significant difference between groups at $p \leq 0.05$

	PVD group	Pain-free group	t-test
	M ± SD	M ± SD	p-values
Pain during MVC	2 ± 2	0 ± 1	*0.03
Pain during PPS testing	6 ± 1	6 ± 1	0.19

Table 4 Participants' demographic information

Notes: Results expressed in numbers and percentages. PVD = provoked vestibulodynia

	PVD group		Pain-free group	
Subjective evaluation	n/11	%	n/11	%
Primary PVD	7	64	-	-
Secondary PVD	4	36	-	-
Smoking	0	0	0	0
Hormonal contraceptive use	8	73	9	82
Full-time student	9	82	11	100
In a relationship	10	91	5	46
Irritable bowel syndrome	2	18	0	0
Constipation (≥1x/month)	4	36	2	18
Dysmenorrhea (painful periods)	10	91	3	27

4.3 NORMALITY AND VARIANCE TESTS

All data were plotted (Figure 3) and tested for normality using histograms and normal probability plots (Figure 4), and were tested for homogeneity of variance using Levene's test. All but two data points fell within three standard deviations of the mean for the normalized EMG data. The data were not trimmed. All normality and variance tests were non-significant, with the exception of the pain ratings recorded during the PPS application (Levene's test-statistic=6.64, $p=0.011$). In the case of the pain ratings, both parametric (T-value=1.19, $p=0.240$) and non-parametric statistics (i.e., Kruskal-Wallis, $H=1.55$, $p=0.214$) found no significant difference between the groups on pain ratings. For the sake of uniformity, parametric statistics were thus used to compare the pain ratings between the groups. This is discussed in more detail in section 4.8.

Figure 3 Raw EMG PFM response activity

Notes: Typical 10-second sample of PFM EMG response data during the PPS application. EMG amplitudes are expressed in microvolts (μV) and time in seconds (s) recorded from the left superficial PFM channel in a control participant. The vertical line indicates the time at which the PPS was applied.

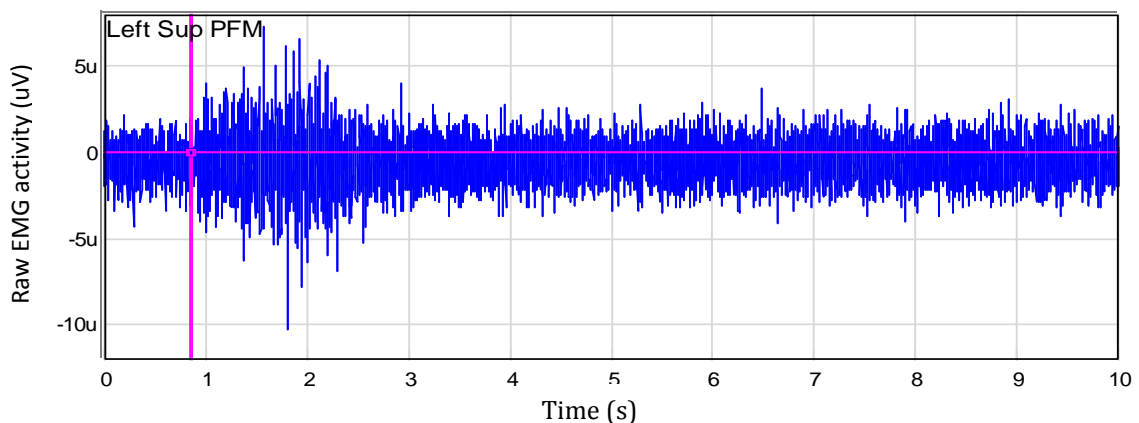
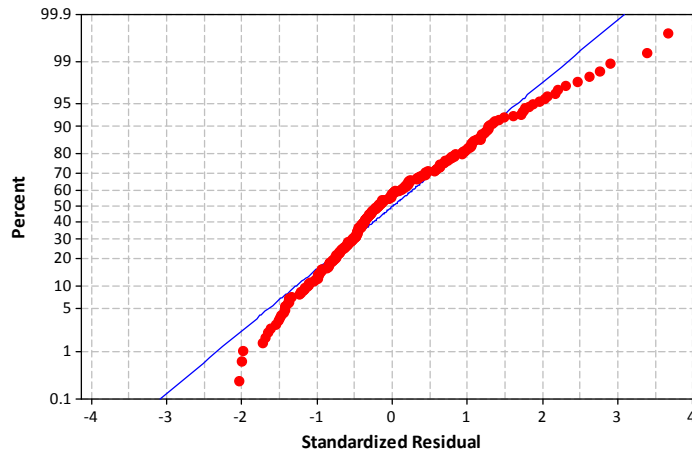


Figure 4 Probability plot of the residuals for normalized EMG responses

Notes: Standardized residuals of normalized PFM EMG responses (% MVE) of participants in both groups and at both muscle layers are presented. Each data point represents one of three PPS trials per women for a total of 66 points.



4.4 BILATERAL MVE ACTIVATION

Data from both the right and left PFMs were recorded throughout the testing. To investigate differences in right and left sided activity of the PFMs, we used the peak amplitudes of the smoothed RMS EMG data (in microvolts [uV]) recorded during the MVC, and compared EMG amplitudes in both the deep (and superficial PFMs. There were no significant differences between sides and groups for raw MVE amplitudes in either the deep ($F=1.05$, $p=0.31$; Figure 5) or superficial ($F=0.99$, $p=0.32$; Figure 6) PFMs. Raw EMG activity from the deep and superficial PFMs were investigated separately. No between layers comparisons were made, due to the fact that comparison of raw data between different recording methods (i.e., Femiscan™ probe vs Harris electrodes) is not appropriate.

Figure 5 Bilateral deep PFMs raw MVE peak amplitudes

Notes: Amplitudes expressed in microvolt (uV). Bars indicate means, and error bars indicate 95% confidence intervals (CI).

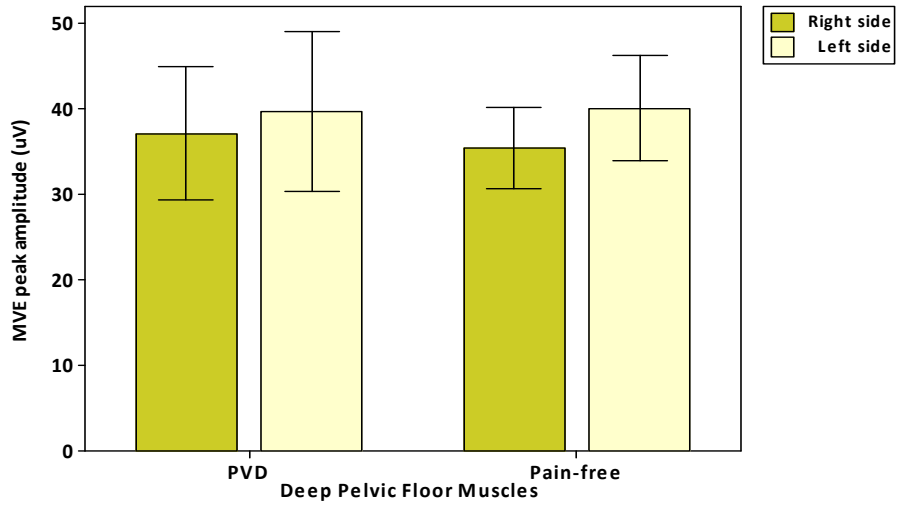
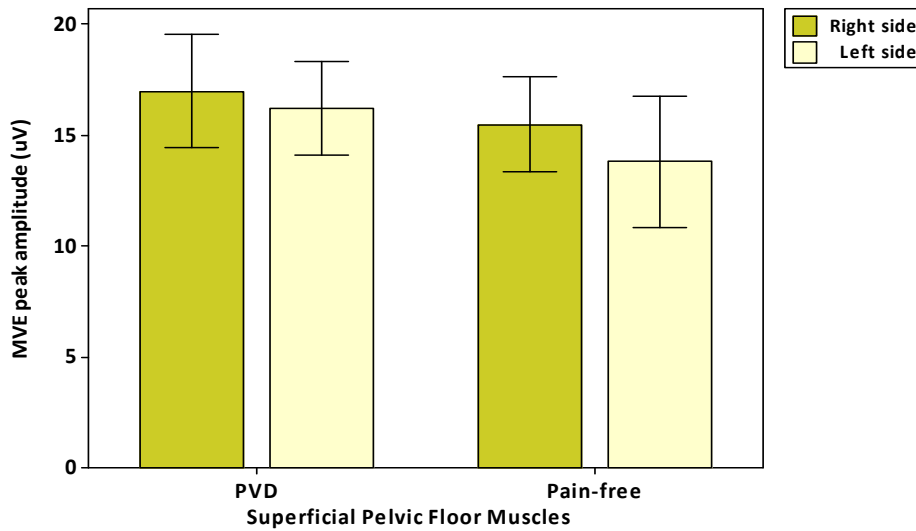


Figure 6 Bilateral superficial PFMs raw MVE peak amplitudes

Notes: Amplitudes expressed in microvolt (uV). Bars indicate means, and error bars indicate 95% CI.



Considering there were no interactions or significant difference in raw MVE EMG amplitudes between muscle sides or groups, the right and left sided data for each muscle were collapsed for all further analyses. Once collapsed, MVE data were not significantly different between groups at either the deep ($F=0.04$, $p=0.85$) or superficial ($F=2.62$, $p=0.11$) PFM layers, which meant that the data could be normalized by the MVE at each muscle site without introducing bias.

4.5 H_A1: IS EMG RESTING ACTIVITY OF THE SUPERFICIAL AND DEEP PFMS DIFFERENT BETWEEN MUSCLE LAYERS AND GROUPS?

The resting activity was not significantly different between groups in the deep PFMs (PVD= Mean $4.81 \pm$ SD $2.71 \mu\text{V}$; Pain-free=Mean $3.97 \pm$ SD $2.28\mu\text{V}$; $F=2.53$, $p=0.12$; Figure 7) while the resting activity of the superficial PFMs in the pain-free group was significantly lower (PVD= Mean $3.06 \pm$ SD $1.89 \mu\text{V}$; Pain-free=Mean $2.35 \pm$ SD $0.86 \mu\text{V}$; $F=4.68$, $p=0.04$; Figure 8) than that recorded from the PVD group. Deep and superficial PFMs EMG resting activity data were not compared.

The mean pressure-pain stimulus (PPS) intensity applied at the vulvar vestibule to cause a moderate level of pain was significantly higher in the pain-free group (Mean= $577 \pm$ SD 184 g;) when compared to the PVD group (Mean $376 \pm$ SD 278 g; $F=11.93$, $p=0.001$; Figure 9). A plot of PPS (in grams of pressure) vs pain ratings (NRS ratings) is presented in Figure 10. Pain ratings and PPS varied such that all women did not report a pain of 6 out of 10 for all pain trials nor did all report pain at the same PPS, which explains the difference in number of data points between groups. There were no correlations between the amount of pressure applied and the NRS pain ratings in either group.

Figure 7 Mean RMS resting EMG amplitudes for the deep PFMs

Notes: Right and left sides combined. Bars indicate means, and error bars indicate 95% CI.

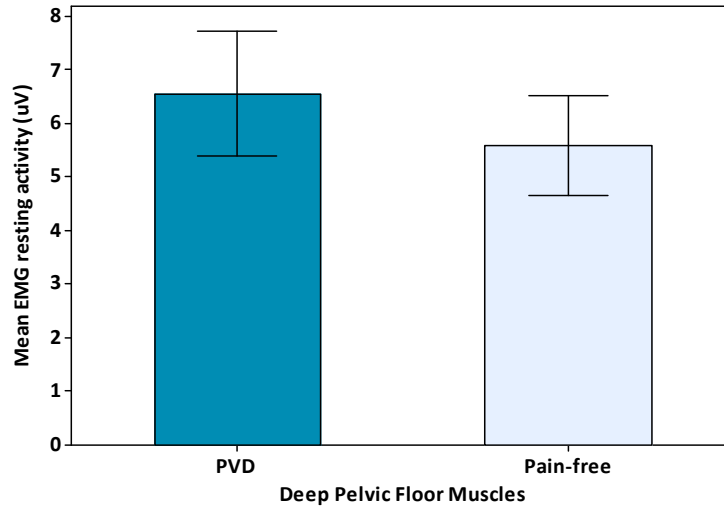


Figure 8 Mean RMS resting EMG amplitudes for the superficial PFMs

Notes: Right and left sides combined. Bars indicate means, and error bars indicate 95% CI. * represent significant difference between groups at $p \leq 0.05$

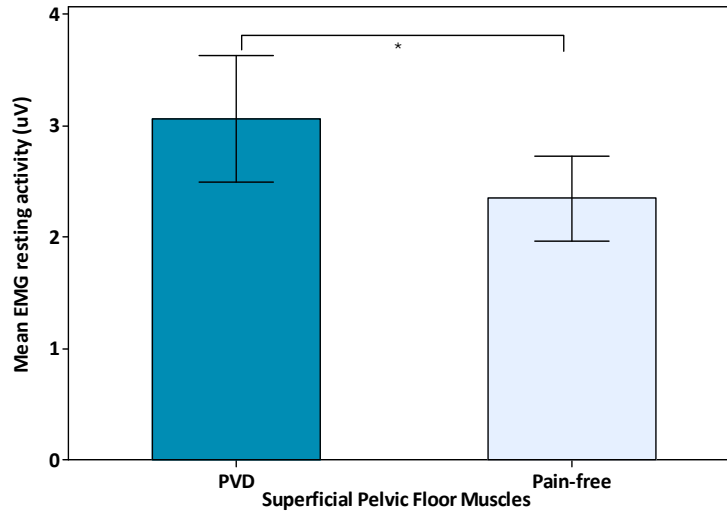


Figure 9 Mean PPS applied to generate a pain intensity of 6/10

Notes: Bars indicate means, and error bars indicate 95% CI. * represent significant difference between groups at $p \leq 0.05$

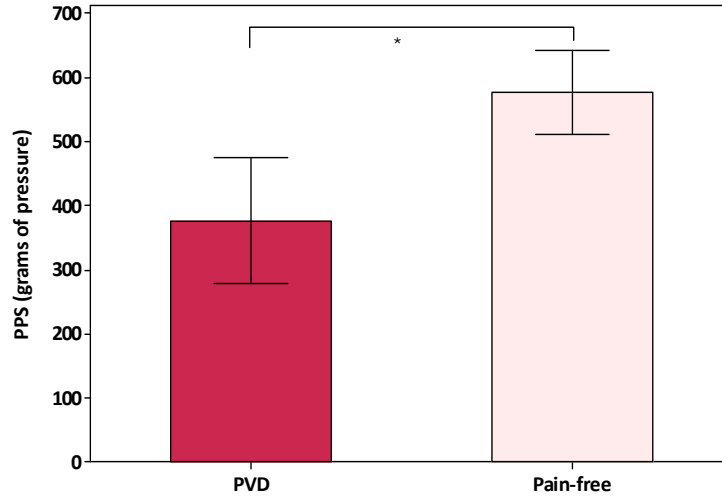
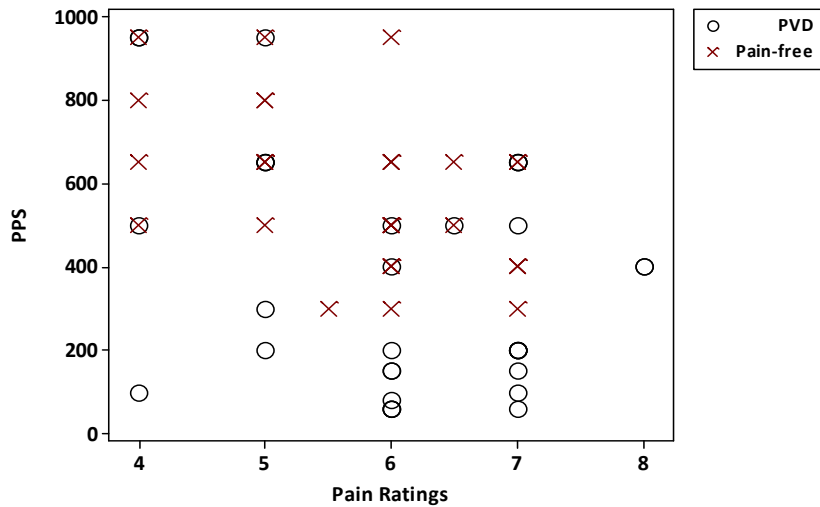


Figure 10 Plot of PPS vs pain ratings upon the application of the PPS

Notes: Each data point represents a PPS pressure level vs. the pain ratings upon the three data trials used to report PFM pain responses for each woman.



4.6 H_A2, 3 & 4: ARE THE SUPERFICIAL AND DEEP PFM RESPONSES TO THE PPS DIFFERENT BETWEEN MUSCLE LAYERS AND GROUPS?

To address our hypotheses both raw and normalized EMG data were analyzed.

There was no significant difference between groups in deep PFMs raw EMG response amplitudes (PVD=Mean 7.08 ± SD 3.16 μV; Pain-free= Mean 7.25 ± SD 3.12 μV; F=0.010, p=0.749; Figure 11). In the superficial PFMs, the raw EMG response amplitudes were significantly higher in the PVD group (PVD=Mean 7.63 ± SD 3.69 μV; Pain-free= Mean 5.20 ± SD 3.73 μV; F=14.3, p ≤ 0.0005; Figure 13) as compared to the pain-free group.

Figure 11 Raw EMG response amplitudes of the deep PFMs

Notes: Bars indicate means, and error bars indicate 95% CI.

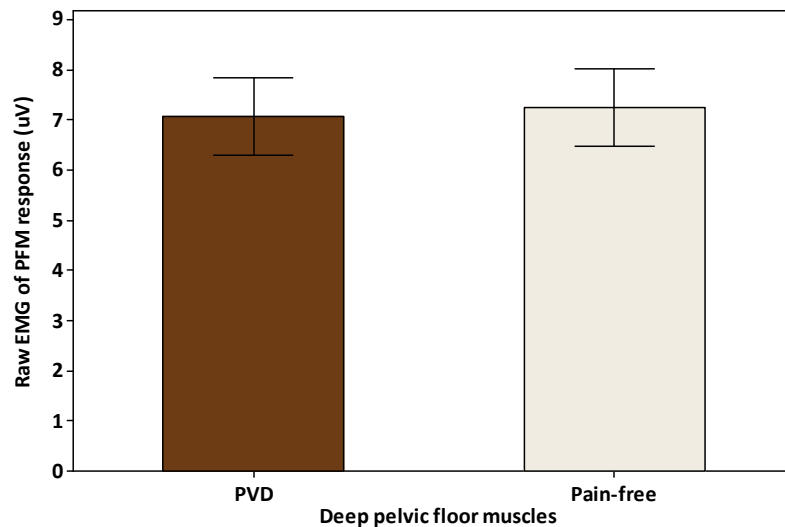
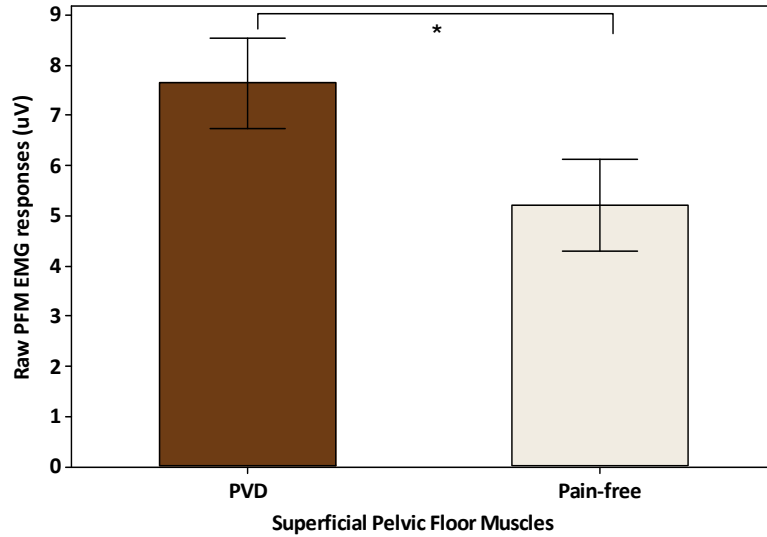


Figure 12 Raw EMG response amplitudes of the superficial PFMs

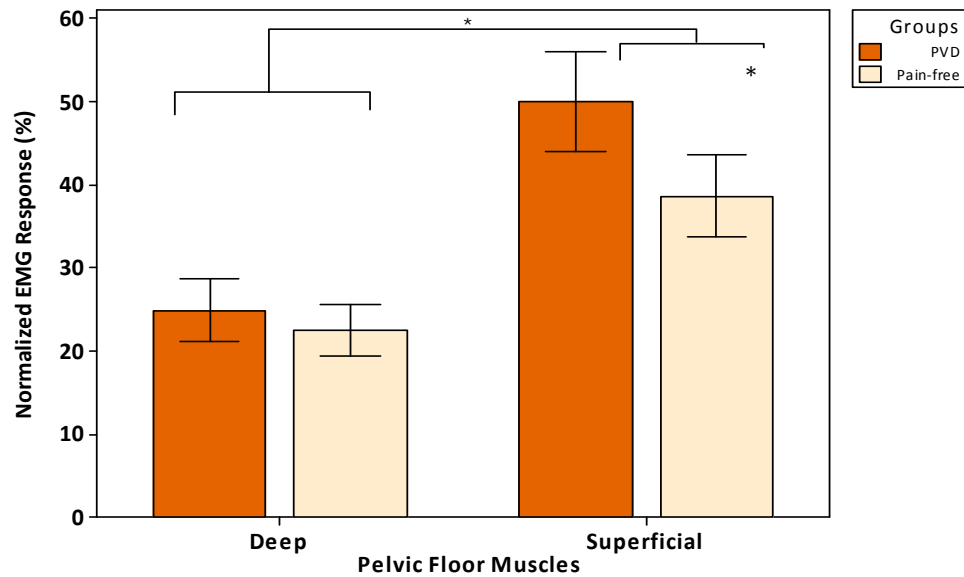
Notes: Bars indicate means, and error bars indicate 95% CI. * represent significant difference between groups at $p \leq 0.05$



There were also observable increases in normalized PFM EMG activity after the application of the PPS. In the pain-free women, responses were seen in both the deep (Mean $22.52 \pm SD 12.59$ %MVE) and superficial (Mean $38.69 \pm SD 20.32$ %MVE) PFMs. The response amplitudes were significantly higher in the superficial PFMs ($F=30.18$, $p=0.0001$) than those observed in the deep PFMs (Figure 13). Women with PVD also demonstrated increases in PFM EMG activity in response to the PPS application in both the deep (Mean $24.88 \pm SD 15.44$ %MVE) and superficial PFMs (Mean $50.06 \pm SD 23.87$ %MVE) PFMs. The response amplitudes were again higher in the superficial PFMs ($F=50.70$, $p=0.0001$) as compared to the deep PFMs (Figure 13).

Figure 13 Normalized %MVE responses

Notes: Bars indicate means, and error bars indicate 95% CI. * represent significant difference between groups at $p \leq 0.05$



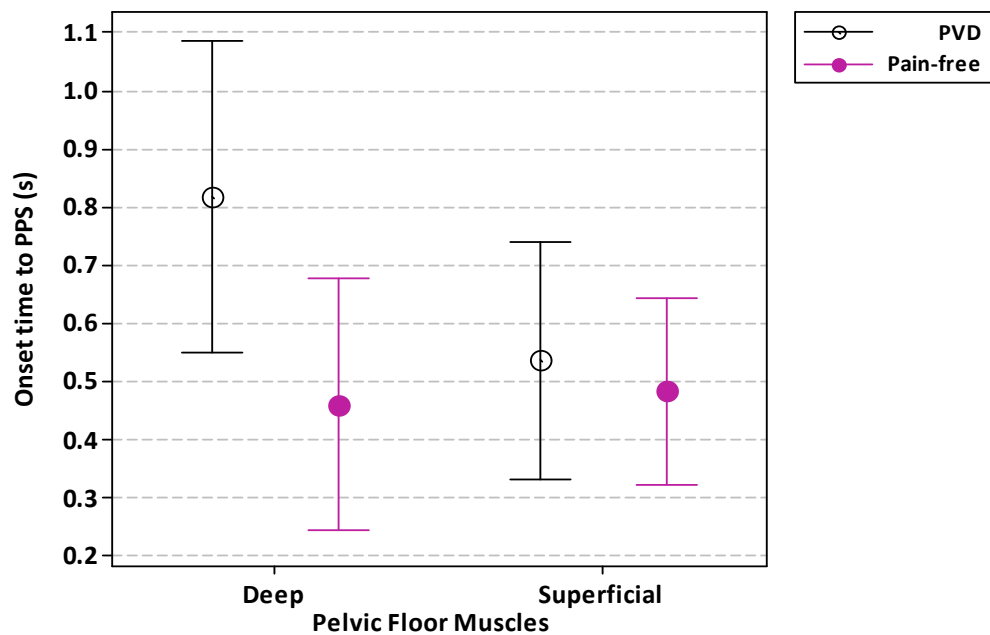
4.7 H_A5 & 6: DO PFM PAIN RESPONSES PRECEDE OR FOLLOW THE PPS AND HOW DOES THIS PATTERN COMPARE BETWEEN MUSCLE LAYERS AND GROUPS?

There were no differences between the respective superficial and deep PFMs onset times (i.e., latency; Figure 14) or in the timing of the PFM activation relative to the delivery of the PPS. There was no muscle layer main effect ($F=1.49$, $p=0.225$), and no muscle layer by group interaction ($F=2.07$, $p=0.153$). Analysis showed a trend towards a group main effect ($F=3.75$, $p=0.056$) at the deep PFMs such that the PVD group had a trend towards a later onset time at the deep PFM layer than the control group. These results show a trend of the deep PFMs being activated after the superficial PFMs in the PVD group only. A post-hoc

power analysis revealed that 52 participants per group would have been necessary for this trend to reach significance, and 159 participants per group would have been needed to detect a difference between deep and superficial PFM layers. Both muscle layers were activated after the application of the PPS, as determined by the CIs not crossing zero (Figure 14).

Figure 14 Interval plot of onset times of the deep and superficial PFMs

Notes: Results are presented in seconds after the application of the PPS. Bars indicate means, and error bars indicate 95% CI.

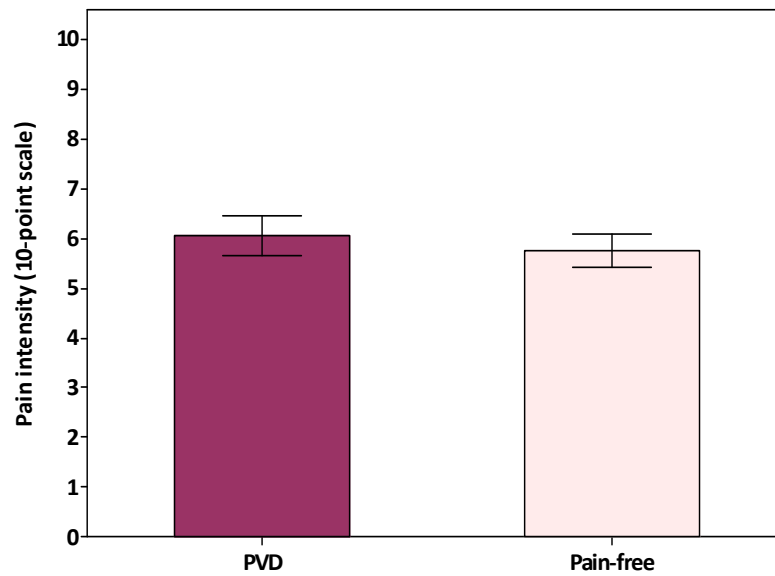


4.8 PAIN RATINGS & PPS

Despite the wide variability in pain ratings across groups, as discussed in section 4.3, the groups did not demonstrate a significant difference in mean pain ratings during the PPS testing, which was confirmed by both parametric ($F=1.41$, $p=0.24$) and non-parametric statistical tests (MannWhitney; $p=0.168$; Figure 15).

Figure 15 Pain ratings upon PPS between groups

Notes: Bars indicate means, and error bars indicate 95% CI.



CHAPTER 5 DISCUSSION

Overall, the findings showed that the women with PVD showed higher resting activity in their superficial PFMs but not their deep PFMs as compared to pain-free women. Both groups of women demonstrated superficial PFM responses to the PPS that were larger than the deep PFM responses; women with PVD showed larger responses than the women without PVD in the superficial PFM layer only. Both groups had PFM responses that followed rather than preceded the PPS in both muscle layers. There was no difference in the timing of the superficial PFM responses between the groups. These results suggest that the PFMs EMG resting activity and response amplitudes of the superficial, but not the deep PFM, are exaggerated in women with PVD, and that these responses are reactive to the pain and not anticipatory. A discussion of these results in the context of the current literature is provided below.

5.1 PARTICIPANT CHARACTERISTICS

The study groups did not differ in age, and are thus equally representative of young women aged 18 to 25. The study groups did not differ in hormonal contraceptive use. Sensitivity to pain has been shown to be influenced by hormonal contraceptive use such that pain thresholds are thought to be lower in the perimenstrual phases in women who are not taking hormonal contraceptives (Isselee, De Laat, Bogaerts, & Lysens, 2001). Since our groups did not differ in terms of hormonal contraceptive use and cycle day on which the testing was performed, group differences found in this study are not likely to be attributable

to differences in hormonal levels. The author was also successful at avoiding testing during the participant's menstrual phase and tested women close to the same time of day.

Primary PVD (i.e., the pain of PVD occurred upon first vaginal penetration) and secondary PVD (i.e., the pain of PVD occurred after non-painful vaginal penetration had occurred) have been suggested to have different etiologies or pathogeneses (Granot et al., 2004; Granot & Lavee, 2005). Women with primary PVD have been found to demonstrate lower blood pressure, higher trait-anxiety and an enhanced systemic pain perception compared to women with secondary PVD (Granot et al., 2004). The study sample included a mix of women with primary (n=7) and secondary (n=4) PVD. There may be differences in the PFM responses between women with primary vs. secondary PVD that were missed by the stratification, since the small sample size did not allow for an appropriate comparison of muscle resting activity, timing, and pain responses between the two sub-types.

5.2 PFM EMG ACTIVITY DURING MVE

The groups differed in terms of reported pain during the performance of the MVE contraction, such that women with PVD had higher (Mean $2 \pm SD 2$) pain ratings than control women (Mean $0 \pm SD 1$). Pain upon contraction was expected to occur, and it was thought that pain might inhibit PFM contraction, and thus lower the MVE amplitudes (Verbunt et al., 2005) in women with PVD. Muscle inhibition would have prevented the normalization of PFM response data because the MVE amplitudes would not have been representative of a true MVE. With lower MVE values, the normalized PFM responses of women in the PVD group would have been biased to higher levels. However, the EMG peak

amplitudes during the MVE did not differ between groups at either the deep or superficial PFMs, which suggested that the pain did not significantly influence MVE amplitudes in women in the PVD group. This finding permitted for the normalization of the PFM response amplitudes to the MVE, which then allowed to appropriately compare the normalized data between PFM layers and between groups. If there had been a systematic difference in MVE amplitudes between groups, normalization would not have been appropriate. The MVE findings are consistent with Engman et al. (2004) who found no difference in EMG MVE amplitudes between 106 women with PVD and 27 pain-free women.

5.3 DIFFERENCE IN PFM RESTING EMG ACTIVITY BY MUSCLE LAYER AND GROUP

Supporting H_{a1} , mean raw resting EMG activity did not differ between the groups in the deep PFMs, while the activity of the mean raw resting EMG activity in the superficial PFMs was significantly higher in the PVD group when compared to the pain-free women. Deep PFMs EMG resting activity results of this study are consistent with previous literature. Engman et al. (2004) found no difference in resting baseline in women with PVD (n=104) when compared pain-free women (n=30), van der Velde & Everaerd (1999) found no difference in baseline activity in two different studies comparing women with vaginismus (n=67) to healthy women (n=43). On the other hand, EMG resting activity from the superficial PFMs did differ between groups in our study, and in this regard, the findings are not consistent with those studies referred to above. This discrepancy might be explained by the fact these two studies did not specifically differentiate between resting EMG activity of the deep versus the superficial PFMs, and their methodology suggests that they were

recording EMG predominantly from the deep PFMs as opposed to the superficial PFMs. Shafik & El-Sibai (2002) investigated the PFMs using needle EMG to compare seven women with vaginismus to seven women without vaginismus. The EMG resting activity of the BC muscle and the LA muscles were higher in women with vaginismus as compared to pain-free women; a finding consistent with the results from this study. These findings of higher EMG resting activity in the superficial PFMs are also consistent hypotheses (Glazer et al., 1995; McKay et al., 2001; White et al., 1997) and findings (Jantos, 2008) from previous studies.

Previous reports did not account for the duration of PVD symptoms when investigating PFM activity in women with PVD. Jantos (2008) recently reported that in 529 women with vulvodynia, EMG resting activity was influenced by the duration of their condition, when age was controlled as a confounder. This fact could account for part of the variability in research results thus far. Pearson correlations for the deep ($p=0.51$) and superficial PFMs ($p=0.16$) resulted in non-significant associations between the duration of PVD symptoms and resting EMG activity. Most studies have included women with co-occurring PFM disorders (e.g., urinary incontinence and vaginismus) and are thus not representative of the PFM functioning in women with PVD exclusively. In the current study, women with any other signs or symptoms of pelvic floor or pelvic pain dysfunction were excluded so that results would reflect PFM functioning in women with PVD exclusively. Lastly, most researchers do not clearly describe their testing position. Surface EMG is highly sensitive to crosstalk from the hip musculature. If women were already contracting their hip muscles, specifically their adductors and internal rotators to support their legs during

the recordings, differences in resting EMG activity might have been missed due to a large amount of crosstalk in the resting EMG activity.

This study highlights the need to separately evaluate the deep and superficial PFMs, since it was found that only the superficial PFMs demonstrate a significantly higher EMG resting activity in women with PVD. This finding is in agreement with the digital palpation findings that superficial PFMs appear to have a higher resting tone than the deep PFMs in women with PVD (Reissing et al., 2004). Also, the lack of difference between EMG resting activity in the deep PFMs between our two groups seems to support the hypothesis that the deep PFMs are not hypertonic at rest, but simply reactive to pain (Reissing et al., 2005).

5.4 RIGHT AND LEFT SIDED EMG SIGNALS BY MUSCLE LAYER

Overall, there were no differences observed between the right as compared to the left side in the EMG resting amplitudes, MVE amplitudes, and response amplitudes recorded from of the deep or superficial PFM layers, and this was the case in both groups. As such, the right and left sided data were collapsed in subsequent analyses. Previous research has shown a high between-day and between-side variability (Madill & McLean, 2006; Brown, 2008) in the deep PFM EMG amplitudes using the Femiscan™ probe. The authors have suggested that the rigid nature of the probe and differences in vaginal anthropometry may cause the probe to tilt to one side, causing that side of the PFM to have better contact with the electrodes, which in turn generates unequal EMG amplitudes between the right and left sides. Having the subjects in the experiment hold the probe straight and in place, which was not done in previous research, might have improved the ability of the probe to record equal

amplitude signals from both sides. It was not expected that there would be a side-to-side difference in recording amplitude in the superficial PFMs since the BC muscles' EMG data were recorded using surface electrodes placed directly over each muscle.

5.6 DIFFERENCE IN PFM EMG RESPONSE AMPLITUDES TO A PPS BY MUSCLE LAYER AND GROUP

Supporting H_{a2}, both women with and without PVD showed PFM responses to the PPS. As previously discussed, raw EMG data in the current study should not be compared across muscle sites unless normalized, since differences in electrode geometry, electrode-skin impedances, inter-electrode distances, and tissue filtering would undoubtedly affect signal amplitude differently at each site. Therefore, the data were normalized to an MVE in order to compare the responses between the deep and superficial PFMs. There are two limitations to our data analysis with respect to normalization. First, the norm in EMG research is to normalize to the mean amplitude of three MVEs rather than one, as is the case in this study. Participants were requested to perform only one contraction in order to minimize the pain caused by the vaginal probe when performing an MVE. Second, MVE is perhaps not the best approach to normalize EMG data from the PFMs. Indeed, studies have shown that 30% of women do not contract their PFMs correctly at their first consultation (Bø & Sherburn, 2005; Bump, Hurt, Fantl, & Wyman, 1991) and thus MVE contractions are expected to be inconsistent across women. Preliminary practice is recommended to help minimize this problem (Merletti, 1999), and thus in the current study women were screened and instructed on how to perform a PFM contraction during the visual examination before initiation of the EMG testing. Yet another important problem when

recording MVEs from the PFMs is the impossibility to correlate EMG activity to a measurable force (Merletti, 1999). The use of an ITT might have solved this problem, however, given that the women already have pain, this methodology would have likely severely limited recruitment. Thus, for the purpose of this study, where possible, the data were analyzed using both the non-normalized and normalized data, and both analyses showed similar results, further strengthening the study's conclusions.

H_{a3} was supported through analyzing the normalized deep and superficial PFM response amplitudes, where it was found that the superficial PFMs responded to a larger extent than the deep PFMs in both groups. These results suggest that the superficial PFM layer might play a bigger role in protective reactions at the vaginal opening than the deeper layer. No previous research has specifically addressed responses to provoked pressure-pain in the PFMs, and no objective measures have been used to compare differences between deep and superficial PFMs activation as responses, limiting the comparability of the current findings to the published literature. However, van der Velde & Everaerd (2001) showed higher PFM activation levels in response to a psychological stress (i.e., a threatening film) as compared to a non-stressful situation (i.e, a neutral film) in both PVD and healthy control women. The authors suggested that the PFMs are part of a general defensive mechanism to threats, and our results support this hypothesis since both of our samples showed EMG responses to the PPS. When considering the results of the current study, it appears that the PFMs contract in response to both psychological (van der velde & Everaerd, 2001) and physical threats, and that the superficial PFMs respond to a larger extent. These higher responses of the superficial PFMs likely occur due to the functional anatomy of the PFMs,

where a contraction of the superficial PFMs acts to close the vaginal opening which would serve as a protective response to threats of unwanted and/or anticipated painful vaginal penetration.

On another note, Flor et al. (1985; 1991; 1996) repeatedly showed that muscular reactivity to psychological stress was site-specific in a population, amongst others, of temporo-mandibular joint dysfunction participants. Indeed, using EMG, they showed that muscular responses would be greater at the site of the pain (e.g., masseter muscle) rather than at remote locations (e.g., trapezius muscle). The authors concluded that hyper-reactivity of the muscular system in chronic pain is an important contributor in the maintenance of pain symptoms (Schneider et al., 2004). These results were similar when a sample of chronic low back pain patients were studied (Glombiewski, Tersek, & Rief, 2008), whereby in response to psychological stressors, and when compared to a pain-free group, the lower paraspinal muscle EMG activity was higher than that seen in the trapezius or upper paraspinal muscles. The hypothesis that muscle responses to pain are site-specific in patients with chronic pain syndromes is supported by the current study, where only the superficial PFMs appear to have heightened responses to a PPS.

In support of H_a4, the superficial PFM responses in women with PVD were significantly higher than those of the pain-free group, suggesting that the superficial PFMs are more responsive in women with PVD than in pain-free women. These results are consistent with the findings of Reissing et al. (2005) who found higher PFM tone in the superficial as compared to the deep PFM layer upon intra-vaginal digital palpation in a sample of women with PVD but not in a pain-free control group. Using needle EMG

recordings during vaginal penetration using a dilator and in a sample of women with and without vaginismus, Shafik & El-Sibai (2002) found higher responses in the superficial BC muscle relative to the deep LA PFMs.

5.7 DIFFERENCE IN PFM ONSET TIME BY MUSCLE LAYER AND GROUP

Contrary to the predictions made by H_a5, the deep and superficial PFM layers in both study groups were activated after the application of the PPS; no evidence of an anticipatory response was seen in the women with PVD. Reissing et al. (2005) observed a protective PFM reaction only upon painful intra-vaginal digital palpation and had thus suggested that palpable PFM hypertonicity is reactive rather than pre-existing in women with PVD, which is consistent with the absence of anticipatory PFM protective responses in the current study. The results are also consistent with the preliminary results of a recent study by Lahaie et al. (2008) who studied women with PVD and women with vaginismus and showed that during a gynecological examination, women with vaginismus demonstrated anticipatory and protective responses (e.g., closure of the legs, termination of the testing protocol prematurely, and contraction of the PFMs) before intra-vaginal assessment, whereas the women with PVD showed no anticipatory responses.

Contrary to the expectation reflected in H_a6, there were no differences between the onset times of the superficial PFMs between the women with PVD and pain-free women. The deep PFMs in the PVD group were, if anything ($p=0.056$), activated later than the deep PFMs of women in the pain-free group, further suggesting that the deep PFMs are not of primary importance in the pain response of women with PVD. Devreese et al. (2007) found

that superficial PFMs were consistently activated before the deep PFMs upon a voluntary contraction in a population of continent perimenopausal parous women, but that this recruitment pattern was not consistent in a group of incontinent women. Their findings suggested a time delay of 21 milliseconds between the superficial and deep PFMs. The trend in the onset timing (i.e., latency) results point towards a different contraction pattern in women with PVD as compared to pain-free women, such that their superficial PFMs seemed to respond to the PPS before the deep PFMs, which, as discussed previously, makes sense if their contraction serves the functional purpose of closing the vaginal entry. That said, the result was not statistically significant and only appeared in the PVD group.

5.8 LIMITATIONS

A major limitation in this study is its small sample size. Indeed the post-hoc power analysis suggests that the low participant numbers might explain why no significant onset time differences were found between groups and muscle layers. That said, no differences in onset times were detected using both parametric and non-parametric statistics, whereas significant differences in response amplitudes were seen in this sample. As such, there was adequate statistical power to detect differences in response amplitudes, although the small sample does limit the generalizability of the results. Subject demographics were in great majority undergraduate Caucasian North American female students which makes it less appropriate to generalize results across races or cultures.

Variables that might have impacted a woman's sensitivity to the PPS and/or the resulting PFM responses include age, hormonal contraceptive use, parity, menstrual cycle,

PPS pressure levels, and pain ratings achieved. Even though as many confounding variables as possible were accounted for, it was impossible to achieve an appropriate matching of all variables between groups. Participants between the groups were recruited based on similar age (within 4 years) and parity. More specific matching would have been more rigorous in terms of methodology and statistical power; however, more tightly controlled matching certainly would have impeded subject recruitment, and thus might still have resulted in power limitations. Post-hoc analysis did reveal that the two groups were not different in terms of other potentially important factors (e.g., oral contraceptive use, and time of testing relative to the menstrual cycle); thus less stringent matching probably did not profoundly affect our results.

Since pain is a subjective experience, PFM responses were compared based on subjective pain ratings of 6 ± 1 out of 10 on a numerical rating scale during the application of the PPS, rather than on the number of grams applied with the vulvalgesiometers. There are three possible experimental issues related to this methodology. First, it was assumed that it is appropriate to compare EMG PFM responses based on pain ratings in order to compare groups on the basis of their perceived pain experience. Perhaps the subjective pain experiences of women with and without PVD felt during the application of the PPS is not reliably assessed using a NRS presented visually. These scales have, however, been shown to be psychometrically sound, highly interpretable, feasible and responsive (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006). In a post-hoc analysis there was no significant correlation between pain ratings and EMG response amplitudes in women with vulvar pain, which is consistent with the published literature (Jantos, 2008), and which supports our

methodology. Second, it is possible that the application of the PPS at the vulvar vestibule caused a muscle stretch, and therefore the observed PFM responses were related to the monosynaptic stretch-reflex rather than behavioural protective PFM responses. This possibility did not seem to be the case, however, since there was no correlation between PFM responses and the level of pressure applied. It is also unlikely that the response latencies reported were caused by a monosynaptic reflex since they were in the range of 300-900 ms, whereas stretch-reflex response are in the range of 30-60 ms (Devreese et al., 2007). Third, as mentioned previously, studies (Flor et al., 1992; Schneider et al., 2004) have demonstrated that heightened muscle responses are related to psychologically stressful stimuli. It is difficult to differentiate how much of the observed PFM responses to the PPS were attributed to the pressure, the pain, and/or psychological stress experienced during the testing. That said, since there were no anticipatory responses seen in this study; presumably, there was not a tremendous amount of psychological stress reflected in the EMG responses measured.

The EMG data normalization process in this study was performed using the EMG amplitudes from only one MVE trial per participant. Typically, in most EMG studies using normalization, normalization is achieved using the average EMG amplitudes based on three MVE trials. The decision to have subjects perform only one MVE was made based on the assumption that the contraction against a rigid probe would provoke vulvar pain in women with PVD, which might then have introduced a fear of pain and therefore would have affected the results from the next two contractions. We were also concerned that causing pain during the initial MVE might have resulted in subjects having more anxiety towards the

protocol, and/or increased sensitivity during testing. Considering that normalization of EMG data from the PFMs is already very imprecise, as discussed previously, it was agreed that one MVE trial would be used, but that we would analyze both the normalized and non-normalized data to interpret our results without bias.

When determining the onset timing of the PFMs, a footswitch was activated by the principal investigator at the time of application of the PPS. This methodology might have introduced a time delay in the order of 100ms in our results, which would have decreased precision in the latencies recorded. Preliminary testing had demonstrated that women's protective responses were significantly slower (averaging 550ms across groups) than any delay between the application of the PPS and the activation of the footswitch. Consequently, the use of a footswitch provided enough precision to answer our study question; whether the PFM EMG responses happened before or after the application of the PPS.

Sampling bias is yet another limitation to this study. Women in both the PVD and the pain-free groups might be different from women that have decided not to participate. Participants might be more comfortable with the invasiveness of the study than the average woman. It is difficult to measure the impact of sampling bias on the current results.

5.9 FUTURE DIRECTIONS

When considering the findings in this thesis relative to the existing literature, it is apparent that authors should report more information on their EMG data in order to facilitate comparison and appraisal of their results. As referred to previously, standards for the reporting of EMG data are published by the International Society of Electrophysiology

and Kinesiology(ISEK) in the Journal of Electromyography and Kinesiology, yet these standards are not adhered to by authors in this field. As previously addressed, surface EMG can be a sensitive way of quantifying muscular responses; however, it is necessary to report the exact testing position, details of the EMG system and set-up, as well as data analysis and quantification parameters.

More controlled research needs to be conducted using larger samples to further investigate PFM onset timing. This part of the study was seemingly under-powered and could not uncover the suspected differences in contraction timing and recruitment patterns between deep and superficial PFM layers in women with and without PVD.

More investigation on the differentiation of the superficial and deep PFMs are needed in order to determine whether the PFM protective responses seen in this work are mediated by a monosynaptic stretch-reflex, as opposed to the pressure sensors in the vulvar vestibule. Such a research result might be achieved using a rectal probe to measure the EMG responses while a vaginal stretch is performed using a device that can provide a standardized stretch at the vaginal opening (for the superficial PFMs) or within the vaginal canal (for the deep PFMs). An alternative would be to investigate the BC reflex with surface and intravaginal electrodes in situ.

Future research should look at the difference between the deep and superficial PFMs in different subtypes of vulvodynia, such as primary and secondary PVD, generalized vulvodynia, vaginismus and other pelvic floor pain disorders. If present, it would then be useful to determine whether pelvic floor physiotherapy can modify and perhaps even reverse the heightened reactions seen in the superficial PFMs. The impact of PFPT on the

PFM responses across diverse conditions would give us insight into better PT treatment techniques.

Lastly, it would be beneficial to conduct a longitudinal study to determine whether the heightened responsiveness of the superficial PFMs found in the current study is present before the onset of vulvodynia, thus answering the long-standing question; is PFM dysfunction a cause or an effect of PVD? The women with PVD who participated in this study took part in a subsequent treatment study using PFPT. The author will soon be able to determine whether the PFPT normalized the higher resting activity and the higher response amplitudes seen in their superficial PFM data.

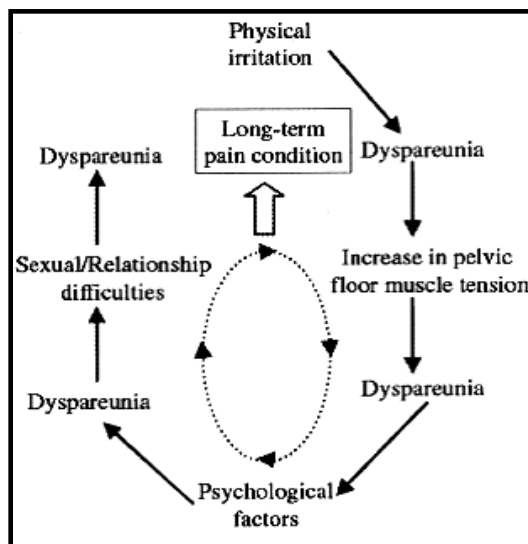
5.10 IMPLICATIONS & CONCLUSIONS

Overall, the results point towards the occurrence of a superficial PFM dysfunction in women with PVD. Heightened protective muscular responses in chronic pain conditions are thought to occur, and may contribute significantly to perpetuating this pain disorder. Specific to PVD, superficial PFMs, more so than deep PFMs, appear to be impaired such that they are hypertonic and over-responsive in women with PVD. The EMG findings may illustrate an enhanced reaction of the superficial PFMs in women with PVD and may support the hypothesis of the vicious pain cycle (Pukall et al., 2005) as illustrated in Figure 16. In this hypothesis, the initial physical irritation (e.g., fissures, repetitive yeast infections, inflammatory process, etc.) that occurs at the vulvar vestibule leads to dyspareunia (i.e., painful intercourse). Dyspareunia then may then cause PFM contractions upon attempted vaginal penetration which in turn increase the pressure and friction on the vulvar vestibule

tissues thus causing more vulvar pain, and eventually relationship, sexual and psychological difficulties.

Figure 16 The vicious cycle of pain

Notes: Handbook of Sexual Dysfunction by Pukall, Payne, Khalifé, & Binik. Taylor & Francis, 2005, p.263. Copyright 2008 by Informa Healthcare - Books. Reproduced with permission of Informa Healthcare - Books in the format Dissertation via Copyright Clearance Center.



To the author's knowledge, this was the first study to differentiate between superficial and deep PFM responses, providing quantitative data explaining the reactive nature of the PFMs in women with PVD and pain-free women. A notable finding in this study was the higher responsiveness demonstrated by the superficial PFMs to a painful stimulus when compared to the deeper PFM layer in women with PVD. These results further advance our understanding of normal PFM functioning and of PFM dysfunction in

women with vulvodynia. In addition, the findings from this study indicate that activity from the deep and superficial PFM layers should be recorded separately in all future studies on women with PVD.

The knowledge gained through this work should incite clinicians to focus on the superficial PFMs during PFPT treatment to restore normal PFM functioning. This research predominantly draws attention to the protective and responsive involvement of the superficial PFMs in PVD.

REFERENCES

- American Psychiatric Association. (2000). DSM-IV TR: Diagnostic and statistical manual for mental disorders 4th edition. Washington DC: American Psychiatric Press.
- Arnold, L. D., Bachmann, G. A., Rosen, R., Kelly, S., & Rhoads, G. G. (2006). Vulvodynia - characteristics and associations with comorbidities and quality of life. *Obstetrics and Gynecology*, *107*(3), 617-624.
- Babula, O., Linhares, I. M., Bongiovanni, A. M., Ledger, W. J., & Witkin, S. S. (2008). Association between primary vulvar vestibulitis syndrome, defective induction of tumor necrosis factor-alpha, and carriage of the mannose-binding lectin codon 54 gene polymorphism. *American Journal of Obstetrics and Gynecology*, *198*(1), 101-102.
- Barber, M. D., Bremer, R. E., Thor, K. B., Dolber, P. C., Kuehl, T. J., & Coates, K. W. (2002). Innervation of the female levator ani muscles. *American Journal of Obstetrics and Gynecology*, *187*(1), 64-71.
- Basmajian, J.V. & DeLuca, C.J. (1985) *Muscles alive*. Williams & Wilkins; Baltimore, MD.
- Basson, R., Althof, S., Davis, S., Fugl-Meyer, K., Goldstein, I., Leiblum, S., et al. (2004). Summary of the recommendations on sexual dysfunctions in women. *The Journal of Sexual Medicine*, *1*(1), 24-34.
- Basson, R., Leiblum, S., Brotto, L., Derogatis, L., Fourcroy, J., Fugl-Meyer, K., et al. (2004). Revised definitions of women's sexual dysfunction. *The Journal of Sexual Medicine*, *1*(1), 40-48.
- Bergeron, S., Binik, Y. M., Khalifé, S., Pagidas, K., Glazer, H. I., Meana, M., et al. (2001). A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis. *Pain*, *91*(3), 297-306.
- Bergeron, S., Brown, C., Lord, M. J., Oala, M., Binik, Y. M., & Khalifé, S. (2002). Physical therapy for vulvar vestibulitis syndrome: A retrospective study. *Journal of Sex & Marital Therapy*, *28*(3), 183-192.
- Bergeron, S., Khalifé, S., Glazer, H. I., & Binik, Y. M. (2008). Surgical and behavioral treatments for vestibulodynia - two-and-one-half-year follow-up and predictors of outcome. *Obstetrics and Gynecology*, *111*(1), 159-166.
- Bernstein, A. M., Philips, H. C., Linden, W., & Fenster, H. (1992). A psychophysiological evaluation of female urethral syndrome: Evidence for a muscular abnormality. *Journal of Behavioral Medicine*, *15*(3), 299-312.
- Bharucha, A. E. (2006). Pelvic floor: Anatomy and function. *Neurogastroenterology and Motility*, *18*(7), 507-519.

- Bø, K., & Finckenhagen, H. B. (2001). Vaginal palpation of pelvic floor muscle strength: Inter-test reproducibility and comparison between palpation and vaginal squeeze pressure. *Acta Obstetrica Et Gynecologica Scandinavica*, 80(10), 883-887.
- Bø, K., & Sherburn, M. (2005). Evaluation of female pelvic-floor muscle function and strength. *Physical Therapy*, 85(3), 269-282.
- Bø, K., Raastad, R., & Finckenhagen, H. B. (2005). Does the size of the vaginal probe affect measurement of pelvic floor muscle strength? *Acta Obstetrica Et Gynecologica Scandinavica*, 84(2), 129-133.
- Bohm-Starke, N. (2001). Vulvar vestibulitis syndrome -- pathophysiology of the vestibular mucosa. *Scandinavian Journal of Sexology*, 4(4), 227-234.
- Bohm-Starke, N., Hilliges, M., Falconer, C., & Rylander, E. (1998). Increased intraepithelial innervation in women with vulvar vestibulitis syndrome. *Gynecologic and Obstetric Investigation*, 46(4), 256-260.
- Bohm-Starke, N., Johannesson, U., Hilliges, M., Rylander, E., & Torebjork, E. (2004). Decreased mechanical pain threshold in the vestibular mucosa of women using oral contraceptives - A contributing factor in vulvar vestibulitis? *Journal of Reproductive Medicine*, 49(11), 888-892.
- Bohm-Starke, N., Hilliges, M., Brodda-Jansen, G., Rylander, E., & Torebjörk, E. (. (2001). Psychophysical evidence of nociceptor sensitization in vulvar vestibulitis syndrome. *Pain*, 94(2), 177-183.
- Brookoff, D., & Bennett, D. S. (2006). Neuromodulation in intractable interstitial cystitis and related pelvic pain syndromes. *Pain Medicine*, 7, 166-184.
- Brown, C. S., Glazer, H. I., Vogt, V., Menkes, D., & Bachmann, G. (2006). Subjective and objective outcomes of botulinum toxin type A treatment in vestibulodynia: Pilot data. *The Journal of Reproductive Medicine*, 51(8), 635-641.
- Brown, C. (2008). Reliability of electromyography detection systems for the pelvic floor muscles. [Master's Thesis]. Kingston, Ontario, Canada: Queen's University.
- Bump, R. C., Hurt, W. G., Fantl, J. A., & Wyman, J. F. (1991). Assessment of kegel pelvic muscle exercise performance after brief verbal instruction. *American Journal of Obstetrics and Gynecology*, 165(2), 322-329.
- Chiarelli, P., Brown, W., & McElduff, P. (1999). Leaking urine: Prevalence and associated factors in Australian women. *Neurourology and Urodynamics*, 18(6), 567.
- Danielsson, I., Sjöberg, I., & Ostman, C. (2001). Acupuncture for the treatment of vulvar vestibulitis: A pilot study. *Acta Obstetrica et Gynecologica Scandinavica*, 80, 437-441.
- Danielsson, I., Torstensson, T., Brodda-Jansen, G., & Bohm-Starke, N. (2006). EMG biofeedback versus topical lidocaine gel: A randomized study for the treatment of women with vulvar vestibulitis. *Acta Obstetrica Et Gynecologica Scandinavica*, 85(11), 1360-1367.

- de Kruiff, M. E., ter Kuile, M. M., Weijnenborg, P. T. M., & van Lankveld, J. J. D. M. (2000). Vaginismus and dyspareunia: Is there a difference in clinical presentation? *Journal of Psychosomatic Obstetrics and Gynecology*, 21(3), 149-155.
- DeLancey, J. O. (2005). The hidden epidemic of pelvic floor dysfunction: Achievable goals for improved prevention and treatment. *American Journal of Obstetrics and Gynecology*, 192(5), 1488-1495.
- DeLancey, J. O. L. (2002). Fascial and muscular abnormalities in women with urethral hypermobility and anterior vaginal wall prolapse. *American Journal of Obstetrics and Gynecology*, 187(1), 93-98.
- DeLuca, C. J. (1997). The use of surface electromyography in biomechanics. *Journal of Applied Biomechanics*, 13(2), 135-163.
- De Luca, C. J., Adam, A., Wotiz, R., Gilmore, L. D., & Nawab, S. H. (2006). Decomposition of surface EMG signals. *Journal of Neurophysiology*, 96(3), 1646-1657.
- Devreese, A., Staes, F., Janssens, L., Penninckx, F., Vereecken, R., & De Weerd, W. (2007). Incontinent women have altered pelvic floor muscle contraction patterns. *Journal of Urology*, 178(2), 558-562.
- Enck, P., & Vodusek, D. B. (2006). Electromyography of pelvic floor muscles. *Journal of Electromyography and Kinesiology*, 16(6), 568-577.
- Engman, M., Lindehammar, H., & Wijma, B. (2004). Surface electromyography diagnostics in women with partial vaginismus with or without vulvar vestibulitis and in asymptomatic women. *Journal of Psychosomatic Obstetrics and Gynaecology*, 25(3-4), 281-294.
- Farage, M. A., & Galask, R. P. (2005). Vulvar vestibulitis syndrome: A review. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, 123(1), 9-16.
- Frawley, H. C., Galea, M. P., Phillips, B. A., Sherburn, M., & Bo, K. (2006). Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourology and Urodynamics*, 25(3), 236-242.
- Flor, H., Birbaumer, N., Schulte, W., & Roos, R. (. (1991). Stress-related electromyographic responses in patients with chronic temporomandibular pain. *Pain*, 46(2), 145-152.
- Flor, H., Schugens, M. M., & Birbaumer, N. (1992). Discrimination of muscle tension in chronic pain patients and healthy controls. *Biofeedback and Self-Regulation*, 17(3), 165-177.
- Flor, H., Turk, D. C., & Birbaumer, N. (1985). Assessment of stress-related psychophysiological reactions in chronic back pain patients. *Journal of Consulting and Clinical Psychology*, 53, 354-364.
- Flor, H., & Turk, D. C. (1996). Integrating central and peripheral mechanisms in chronic muscular pain - an initial step on a long road. *Pain Forum*, 5(1), 74-76.

- Gerber, S., Bongiovanni, A. M., Ledger, W. J., & Witkin, S. S. (2002). Defective regulation of the proinflammatory immune response in women with vulvar vestibulitis syndrome. *American Journal of Obstetrics and Gynecology*, 186(4), 696-700.
- Glatt, A. E., Zinner, S. H., & McCormack, W. M. (1990). The prevalence of dyspareunia. *Obstetrics and Gynecology*, 75(3 Pt 1), 433-436.
- Glazer, H. I., Rodke, G., Swencionis, C., Hertz, R., & Young, A. (1995). Treatment of vulvar vestibulitis syndrome with electromyographic biofeedback of pelvic floor musculature. *Journal of Reproductive Medicine*, 40(4), 283-290.
- Glazer, H. I., Jantos, M., Hartmann, E. H., & Swencionis, C. (1998). Electromyographic comparisons of the pelvic floor in women with dysesthetic vulvodynia and asymptomatic women. *The Journal of Reproductive Medicine*, 43(11), 959-962.
- Glazer, H. I., Romanzi, L., & Polaneczky, M. (1999). Pelvic floor muscle surface electromyography - reliability and clinical predictive validity. *The Journal of Reproductive Medicine*, 44(9), 779-782.
- Glombiewski, J. A., Tersek, J., & Rief, W. (2008). Muscular reactivity and specificity in chronic back pain patients. *Psychosomatic Medicine*, 70(1), 125-131.
- Goetsch, M. F. (2007). Surgery combined with muscle therapy for dyspareunia from vulvar vestibulitis - an observational study. *Journal of Reproductive Medicine*, 52(7), 597-603.
- Goldstein, A. T., Marinoff, S. C., & Haefner, H. K. (2005). Vulvodynia: Strategies for treatment. *Clinical Obstetrics and Gynecology*, 48(4), 769-785.
- Graber, B., & Kline-Graber, G. (1979). Female orgasm - role of pubococcygeus muscle. *Journal of Clinical Psychiatry*, 40(8), 348-351.
- Granot, M., Friedman, M., Yarnitsky, D., Tamir, A., & Zimmer, E. Z. (2004). Primary and secondary vulvar vestibulitis syndrome: Systemic pain perception and psychophysical characteristics. *American Journal of Obstetrics and Gynecology*, 191(1), 138-142.
- Granot, M., & Lavee, Y. (2005). Psychological factors associated with perception of experimental pain in vulvar vestibulitis syndrome. *Journal of Sex & Marital Therapy*, 31(4), 285-302.
- Gunter, J. (2007). Vulvodynia: New thoughts on a devastating condition. *Obstetrical and Gynecological Surgery*, 12, 812-819.
- Gurel, H., & Gurel, S. A. (1999). Dyspareunia, back pain and chronic pelvic pain: The importance of this pain complex in gynecological practice and its relation with grandmultiparity and pelvic relaxation. *Gynecologic and Obstetric Investigation*, 48(2), 119-122.
- Haefner, H. K. (2000). Critique of new gynecologic surgical procedures: Surgery for vulvar vestibulitis. *Clinical Obstetrics and Gynecology*, 43(3), 689-700.

- Hall, G., & Phillips, T. J. (2005). Estrogen and skin: The effects of estrogen, menopause, and hormone replacement therapy on the skin. *Journal of the American Academy of Dermatology*, 53(4), 555-568.
- Harlow, B. L., & Stewart, E. G. (2003). A population-based assessment of chronic unexplained vulvar pain: Have we underestimated the prevalence of vulvodynia? *Journal of the American Medical Women's Association*, 58(2), 82-88.
- Harlow, B. L., & Stewart, E. G. (2005). Adult-onset vulvodynia in relation to childhood violence victimization. *American Journal of Epidemiology*, 161(9), 871-880.
- Harlow, B. L., Wise, L. A., & Stewart, E. G. (2001). Prevalence and predictors of chronic lower genital tract discomfort. *American Journal of Obstetrics and Gynecology*, 185(3), 545-550.
- Hodges, P. W., Sapsford, R., & Pengel, L. H. M. (2007). Postural and respiratory functions of the pelvic floor muscles. *Neurourology and Urodynamics*, 26(3), 362-371.
- Idama, T. O. & Pring, D. W. (2000). Vaginal dilator therapy-an outpatient gynaecological option in the management of dyspareunia. *Journal of Obstetrics and Gynaecology*, 20, 303-305.
- Isselee, H., De Laat, A., Bogaerts, K., & Lysens, R. (2001). Long-term fluctuations of pressure pain thresholds in healthy men, normally menstruating women and oral contraceptive users. *European Journal of Pain*, 5(1), 27-37.
- Jantos, M. (2008). Vulvodynia: A psychophysiological profile based on electromyographic assessment. *Applied Psychophysiology and Biofeedback*, 33(1), 29-38.
- Johannesson, U., de Boussard, C. N., Brodda-Jansen, G., & Bohm-Starke, N. (2006). Evidence of diffuse noxious inhibitory controls (DNIC) elicited by cold noxious stimulation in patients with provoked vestibulodynia. *Pain*, 130, 31-39.
- Lahaie, M.A., Binik, Y.M, Khalifé, S., Amsel, R., & Pukall, C.F. (2008) Fear and pain vs. muscle spasm as the main diagnostic criteria for vaginismus [PhD Thesis]. Montreal, Quebec, Canada: McGill University. Presented at the Society for Sex Therapy and Research Annual Meeting in Chicago, IL, USA.
- Landry, T., Bergeron, S., Dupuis, M., & Desrochers, G. (2008). The treatment of provoked vestibulodynia: A critical review. *Clinical Journal of Pain*, 24(2), 155-171.
- Laycock, J. (1994). Pelvic muscle exercises: Physiotherapy for the pelvic floor. *Urologic Nursing : Official Journal of the American Urological Association Allied*, 14(3), 136-140.
- Leclair, C. M., Goetsch, M. E., Lee, K. K., & Jensen, J. T. (2007). KTP-nd : YAG laser therapy for the treatment of vestibulodynia - A follow-up study. *Journal of Reproductive Medicine*, 52(1), 53-58.

- Madill, S. J., & McLean, L. (2006). Relationship between abdominal and pelvic floor muscle activation and intravaginal pressure during pelvic floor muscle contractions in healthy continent women. *Neurourology and Urodynamics*, 25(7), 722-730.
- Mann, M. S., Kaufman, R. H., Brown, D., & Adam, E. (1992). Vulvar vestibulitis - significant clinical-variables and treatment outcome. *Obstetrics and Gynecology*, 79(1), 122-125.
- McKay, E., Kaufman, R. H., Doctor, U., Berkova, Z., Glazer, H., & Redko, V. (2001). Treating vulvar vestibulitis with electromyographic biofeedback of pelvic floor musculature. *Journal of Reproductive Medicine*, 46, 337-342.
- Meana, M., Binik, Y. M., Khalifé, S., & Cohen, D. R. (1997). Biopsychosocial profile of women with dyspareunia. *Obstetrics and Gynecology*, 90(4; Part 1), 583-589.
- Merletti, R. (1999). Standards for reporting EMG data. *International Society of Electromyography and Kinesiology*.
- Merton, P. A. (1954). Interaction between muscle fibres in a twitch. *Journal of Physiology*, 124(2), 311-324.
- Metts, J. F. (1999). Vulvodynia and vulvar vestibulitis: Challenges in diagnosis and management. *American Family Physician*, 59(6), 1547-156X.
- Moseley, G. L. (2003). A pain neuromatrix approach to patients with chronic pain. *Manual Therapy*, 8(3), 130-140.
- Moyal, M., & Lynch, P. (2004). 2003 ISSVD terminology and classification of vulvodynia: A historical perspective. *Journal of Reproductive Medicine*, 49(10), 772-777.
- Murina, F., Bernorio, R., & Palmiotto, R. (2008). The use of amielle vaginal trainers as adjuvant in the treatment of vestibulodynia: An observational multicentric study. *The Medscape Journal of Medicine*, 10, 23.
- Nappi, R. E., Ferdeghini, F., Abbiati, I., Vercesi, C., Farina, C., & Polatti, F. (2003). Electrical stimulation (ES) in the management of sexual pain disorders. *Journal of Sex and Marital Therapy*, 29(1), 103-110.
- O'Sullivan, P. (2005). Diagnosis and classification of chronic low back pain disorders: Maladaptive movement and motor control impairments as underlying mechanism. *Manual Therapy*, 10(4), 242-255.
- Payne, K. A., Binik, Y. M., Amsel, R., & Khalifé, S. (2005). When sex hurts, anxiety and fear orient attention towards pain. *European Journal of Pain (London, England)*, 9(4), 427-436.
- Payne, K. A., Binik, Y. M., Pukall, C. F., Thaler, L., Amsel, R., & Khalifé, S. (2007). Effects of sexual arousal on genital and non-genital sensation: A comparison of women with vulvar vestibulitis syndrome and healthy controls. *Archives of Sexual Behavior*, 36(2), 289-300.

- Perrigouard, C., Dreval, A., Cribier, B., & Lipsker, D. (2008). Vulvar vestibulitis syndrome: A clinicopathological study of 14 cases. *Annales de Dermatologie et de Vénérologie*, 135(5), 367-372.
- Peters, K. M., Carrico, D. J., Kalinowski, S. E., Ibrahim, I. A., & Diokno, A. C. (2007). Prevalence of pelvic floor dysfunction in patients with interstitial cystitis. *Urology*, 70(1), 16-18.
- Pukall, C., Kandyba, K., Amsel, R., Khalifé, S., & Binik, Y. (2007). Effectiveness of hypnosis for the treatment of vulvar vestibulitis syndrome: A preliminary investigation. *The Journal of Sexual Medicine*, 4(2), 417-425.
- Pukall, C. F., Binik, Y. M., & Khalifé, S. (2004). A new instrument for pain assessment in vulvar vestibulitis syndrome. *Journal of Sex & Marital Therapy*, 30(2), 69-78.
- Pukall, C. F., Strigo, I. A., Binik, Y. M., Amsel, R., Khalifé, S., & Bushnell, M. C. (2005). Neural correlates of painful genital touch in women with vulvar vestibulitis syndrome. *Pain*, 115(1), 118-127.
- Raez, M. B., Hussain, M. S., & Mohd-Yasin, F. (2006). Techniques of EMG signal analysis: Detection, processing, classification and applications. *Biological Procedures Online*, 8, 11-35.
- Reissing, E. D., Binik, Y. M., Khalifé, S., Cohen, D., & Amsel, R. (2004). Vaginal spasm, pain, and behavior: An empirical investigation of the diagnosis of vaginismus. *Archives of Sexual Behavior*, 33(1), 5-17.
- Reissing, E. D., Brown, C., Lord, M. J., Binik, Y. M., & Khalifé, S. (2005). Pelvic floor muscle functioning in women with vulvar vestibulitis syndrome. *Journal of Psychosomatic Obstetrics and Gynaecology*, 26(2), 107-113.
- Roy, S. H., De Luca, G., Gilmore, L. D., Cheng, M. S., Johansson, A., & De Luca, C. J. (2007). Electro-mechanical stability of surface EMG sensors. *Medical and Biological Engineering and Computing*, 45(5), 447-457.
- Rosenbaum, T. Y. (2005). Physiotherapy treatment of sexual pain disorders. *Journal of Sex & Marital Therapy*, 31(4), 329-340.
- Rosenbaum, T. Y. (2007a). Pelvic floor involvement in male and female sexual dysfunction and the role of pelvic floor rehabilitation in treatment: A literature review. *Journal of Sexual Medicine*, 4(1), 4-13.
- Rosenbaum, T. Y. (2007b). *Physical therapy and sexual health*. Westport, CT, US: Praeger Publishers/Greenwood Publishing Group.
- Schneider, C., Palomba, D., & Flor, H. (2004). Pavlovian conditioning of muscular responses in chronic pain patients: Central and peripheral correlates. *Pain*, 112(3), 239-247.
- Schuessler, B., & Baessler, K. (2003). Pharmacologic treatment of stress urinary incontinence: Expectations for outcome. *Urology*, 62(4), 31-38.
- Shafik, A. (1999). Physioanatomic entirety of external anal sphincter with bulbocavernosus muscle. *Archives of Andrology*, 42(1), 45.

- Shafik, A., & El-Sibai, O. (2002). Study of the pelvic floor muscles in vaginismus: A concept of pathogenesis. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, 105(1), 67-70.
- Shafik, A., Shafik, I. A., El Sibai, O., & Shafik, A. A. (2007). Physioanatomical relationship of the external anal sphincter to the bulbocavernosus muscle in the female. *International Urogynecology Journal*, 18(8), 851-85.
- Seseke, S., Baudewig, J., Kallenberg, K., Ringert, R. H., Seseke, F., & Dechent, P. (2006). Voluntary pelvic floor muscle control - an fMRI study. *NeuroImage*, 31(4), 1399-1407.
- Simons, D. G., & Mense, S. (1998). Understanding and measurement of muscle tone as related to clinical muscle pain. *Pain*, 75(1), 1-17.
- Simons, D. G., & Travell, J. G. (1983). Myofascial origins of low-back-pain - principles of diagnosis and treatment. *Postgraduate Medicine*, 73(2), 66-XX.
- Soderberg, G. L., & Knutson, L. M. (2000). A guide for use and interpretation of kinesiological electromyographic data. *Physical Therapy*, 80, 485-498.
- Stewart, E. G., & Berger, B. M. (1997). Parallel pathologies? vulvar vestibulitis and interstitial cystitis. *Journal of Reproductive Medicine*, 42(3), 131-134.
- Stinson, J. N., Kavanagh, T., Yamada, J., Gill, N., & Stevens, B. (2006). Systematic review of the psychometric properties, interpretability and feasibility of self-report pain intensity measures for use in clinical trials in children and adolescents. *Pain*, 125(1-2), 143-157.
- Sutton, K. (2007). The relationship between psychosocial functioning and diffuse noxious inhibitory control function in women with provoked vestibulodynia and pain free controls [Master's Thesis]. Kingston, Ontario, Canada: Queen's University.
- Thompson, J. A., O'Sullivan, P. B., Briffa, N. K., & Neumann, P. (2006). Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze pressure measurements. *International Urogynecology Journal*, 17(6), 624-630.
- Turker, K. S. (1993). Electromyography: Some methodological problems and issues. *Physical Therapy*, 73(10), 698-710.
- van der Velde, J., & Everaerd, W. (2001). The relationship between involuntary pelvic floor muscle activity, muscle awareness and experienced threat in women with and without vaginismus. *Behaviour Research and Therapy*, 39(4), 395-408.
- Verbunt, J. A., Seelen, H. E., Vlaeyen, J. W., Bousema, E. J., van der Heijden, Geert J., Heuts, P. H., et al. (2005). Pain-related factors contributing to muscle inhibition in patients with chronic low back pain: An experimental investigation based on superimposed electrical stimulation. *Clinical Journal of Pain*, 21(3), 232-240.
- Verit, F. F., & Verit, A. (2007). Validation of the female sexual function index in women with chronic pelvic pain. *Journal of Sexual Medicine*, 4(6), 1635-1641.

- Weijmar Schultz, W., Basson, R., Binik, Y., Eschenbach, D., Wesselmann, U., & van Lankveld, J. (2005). Women's sexual pain and its management. *Journal of Sexual Medicine, 2*, 301-316.
- White, G., Jantos, M., & Glazer, H. I. (1997). Establishing the diagnosis of vulvar vestibulitis. *Journal of Reproductive Medicine, 42*(3), 157-160.
- Wijma, J., Tinga, D. J., & Visser, G. H. A. (1991). Perineal ultrasonography in women with stress-incontinence and controls - the role of the pelvic floor muscles. *Gynecologic and Obstetric Investigation, 32*(3), 176-179.
- Zermann, D. H., Ishigooka, M., Doggweiler, R., & Schmidt, R. A. (1999). Chronic prostatitis: A myofascial pain syndrome? *Infections in Urology, 12*(3), 84-92.
- Zolnoun, D., Hartmann, K., Lamvu, G., As-Sanie, S., Maixner, W., & Steege, J. (2006). A conceptual model for the pathophysiology of vulvar vestibulitis syndrome. *Obstetrical & Gynecological Survey, 61*(6), 395-401.

Appendix A Ethics Approval

QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING
HOSPITALS RESEARCH ETHICS BOARD



June 18, 2007

This Ethics Application was subject to:

- Full Board Review
Meeting Date:
 Expedited Review

Dr. C. Pukall
Department of Psychology
Queen's University

Dear Dr. Pukall,

Study Title: The effectiveness of pelvic floor physiotherapy in women with vulvar vestibulitis (VVS)
Co-Investigators: C. Goldfinger, L. McLean, E. Gentilcore-Saulnier, L. McLean and S. Chamberlain

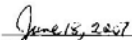
The members of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board have examined the protocol, amendments to the protocol, recruitment flyer, and revised information/consent form (Version 2, June 14, 2007) for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the chair's signature below. Please attend carefully to the following list of ethics requirements you must fulfill over the course of your study:

- **Reporting of Amendments:** If there are any changes to your study (e.g. consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. (see <http://www.queensu.ca/vpr/reb.htm>).
- **Reporting of Serious Adverse Events:** Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information.
- **Reporting of Complaints:** Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. **Note:** All documents supplied to participants must have the contact information for the Research Ethics Board.
- **Annual Renewal:** Prior to the expiration of your approval (which is one year from the date of the Chair's signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year.

Yours sincerely,



Chair, Research Ethics Board



Date

ORIGINAL TO INVESTIGATOR - COPY TO DEPARTMENT HEAD - COPY TO HOSPITAL(S) /P&T (if appropriate) - FILE COPY

Study Code: PSYC-070-07

- **Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete**



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March 21, 2007

Ms. Evelyne Gentilcore-Saulnier
School of Rehabilitation Therapy
Queen's University

Re: "Response of the pelvic floor muscles to vulvar vestibule stimulation"

Dear Ms. Gentilcore-Saulnier,

I am writing to acknowledge receipt of your recent ethics submission for the above-named study. I have reviewed these materials and do not feel that it is necessary for the study to undergo a full REB review. I have therefore given the study an expedited review and an approval sheet is appended for your records. This study will be reported to the Research Ethics Board.

Yours sincerely,

A handwritten signature in cursive script that reads "Albert Clark".

Albert Clark, Ph.D.
Chair
Research Ethics Board

AFC/kr

c.c.: Dr. Linda McLean, School of Rehabilitation Therapy
Dr. Joan Stevenson, School of Kinesiology and Physical Health

think Research
think Queen's

Appendix B Recruitment Pamphlets



Do You Have Pain During Sexual Intercourse?

Are You Looking For a **Treatment** Option For
This Pain?

We are looking for women to participate in a study on the effectiveness of **pelvic floor physiotherapy** on painful intercourse

Study Procedures:

gynecological examination, interview, 10 weekly sessions of pelvic floor physiotherapy, and follow-up sessions

All information is strictly confidential.

****All treatment is provided free of charge****

For more information, please contact the Sexual Health Research Lab

(613) 533-3276

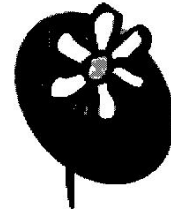
SHRL@queensu.ca

Caroline Pukall PhD, Linda McLean BScPT, PhD, Susan Chamberlain MD
Corrie Goldfinger, BA, MA Student, Evelyne Gentilcore-Saulnier BScPT, MSc Student

Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276	Pain Treatment SHRL@queensu.ca (613) 533-3276
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Are you a woman with NO history of pain during intercourse ?



You can help us!

We are looking for women to participate in a study on the pelvic floor muscle function in women with and without vulvar pain

Study Procedures:

One Gynecological Examination & One Pelvic Floor Muscle Evaluation

All information provided will remain strictly confidential

****Compensation provided****

Interested?

The study is conducted at the School of Rehabilitation Therapy
For more information, please contact the Sexual Health Research Lab

**(613) 533-3276
SHRL@queensu.ca**

Caroline Pukall PhD, Linda McLean BScPT, PhD, Susan Chamberlain MD
Evelyne Gentilcore-Saulnier BScPT, MSc Student, Corrie Goldfinger, BA, MA Student

Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276	Pelvic Floor Muscle Study SHRL@queensu.ca (613) 533-3276
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Appendix C Phone Screening Forms

Telephone Information Sheet: Efficacy of Pelvic Floor Physiotherapy for Women with PVD

Thank you for your interest in the study. First of all, can I ask you where you found out about the study? [fill this in on the screening form pg. 1]

First I am going to tell you about the purpose of this study, as well as the details of what your participation would entail if you are eligible and choose to participate. If you are still interested after the description of the study then I will ask you a number of questions to determine your eligibility for the study. If you are not eligible for this study but would like your name to be added to our lab recruitment database for future studies for which you may be eligible then this can be done at that time. This description and screening questionnaire could take 20 to 30 minutes, and some of the questions are personal in nature. Is now an appropriate time to complete the interview, or would you like us to give you a call back? **[If to call back, get their name and contact information and the best time to reach them]**

Please interrupt me at any time if you have questions. The purpose of this study is to determine the effectiveness of a treatment option known as pelvic floor physiotherapy for women with provoked vestibulodynia or PVD. This was previously called vulvar vestibulitis syndrome or VVS. PVD is a form of chronic vulvar pain which affects approximately 12% of women in the general population. More specifically it refers to pain experienced near the opening of the vagina that usually occurs at times of vaginal penetration; however, it may also be experienced at other times when pressure is applied to the area. We are only including women in this study who have PVD. However if you think you may have PVD but have not been given a diagnosis that is fine; we go through a formal process of determining whether or not you have PVD.

The pelvic floor muscles are the muscles responsible for vaginal, urinary, and anal functioning. For example, these muscles are the ones you would tense up to prevent urination. It is believed that a tightening of the muscles in the pelvic floor contributes to the maintenance and worsening of vulvar pain, and that physiotherapy can thus help reduce this muscle tension, therefore decreasing pain. Although studies have looked at the effectiveness of one of the techniques used in physiotherapy, studies have not assessed pelvic floor muscles tightening, nor have they looked at the effectiveness of a comprehensive program of pelvic floor physiotherapy for women with PVD despite its use in practice today.

Your participation in the study would include several steps. [If you have already participated in one or both of the other PVD studies taking place in the lab, you will still have to go through all of these steps, even if some procedures are the same.] First, you would have a gynecological exam carried out at the Kingston General Hospital with a gynecologist, and a research assistant would be present in the room to take down notes. As Kingston General Hospital is a teaching hospital, it is also possible

that a medical student will attend the gynecological exam. This would be a 15-minute appointment in which the doctor will determine the presence or absence of PVD. If a diagnosis is not made, or cannot be made due to an inability to complete the examination, then participation in the study cannot continue. If a diagnosis of PVD is made then you would come into the Sexual Health Research Lab at the Psychology Department at Queen's University for one 2.5 hour session on a different day. This session would be run by a female graduate student and would include an interview and questionnaire session covering information about sociodemographics, medical, sexual and general pain history, vulvar pain history, general health and emotional well-being, sexual functioning, and relationship functioning if you are currently in a relationship. It also entails sensory testing during which the graduate student will be applying different amounts of pressure to the vestibule, or the area around the opening to the vagina. She will be asking you when you feel touch and pain, and will ask you to rate the intensity and unpleasantness of the sensations. The pressures increase in small increments and stop increasing when you indicate that you can no longer tolerate the pain or when you reach a moderate level of pain. Pressure does not increase to any standard amount for all participants, so the amount of increase will depend entirely on your tolerance levels. Although pain will be experienced during this examination, no health risks are posed and the painful sensations should not last for a long period of time. A female research assistant will be in the room at the time of the sensory testing to record information.

After this session is done, you will be booked in to see the physiotherapy graduate student. She is a registered physiotherapist by the College of Physiotherapists of Ontario who has extensive training and experience using pelvic floor physiotherapy with women with PVD. You will take part in one 1.5-2 hour physiotherapy evaluation at the Queen's University Motor Performance Laboratory at the School of Rehabilitation Therapy. It will consist of an interview of your medical history and symptoms, a pelvic floor physical examination, a pelvic floor biofeedback testing, which I will describe, and an educational session. The graduate student who performed the interview and sensory testing will be at this session to record information. Before starting the pelvic floor evaluation, the physiotherapist will record your heart rate in order to assess your level of stress associated with the procedures. During the pelvic floor evaluation, the physiotherapist will visually and manually evaluate your pelvic floor muscles both externally and internally. This will be done in order to evaluate its capacity to contract and to relax. The pelvic floor examination will be followed by a biofeedback test of your pelvic floor. This involves inserting a small probe into your vagina, with the assistance of the physiotherapist. The probe is hooked up to a computer monitor which will allow recording of the reaction of your pelvic floor muscles during the application of pressure on your vulvar vestibule with a cotton-swab. Finally, the physiotherapist will explain to you the results of the evaluation. She will invite you to ask questions or voice concerns you might have. Much like the sensory testing session, no health risks are posed by the physical therapy assessment techniques and any discomfort you feel should be lower in intensity than the pain you experience with intercourse; it will also be brief (i.e., less than 1 minute).

At this point, you will set up a weekly meeting time with the physiotherapist for treatment sessions. You will complete nine 1-hour weekly pelvic floor physiotherapy treatment sessions. You will also receive a list of daily exercises to perform at home. These exercises take approximately 10 minutes.

One of the main goals of the physiotherapy treatment is to enable you to relax your pelvic floor muscles, which is thought to be the key to diminishing your pain. As such, there might be some discomfort associated with manual intra-vaginal pelvic floor muscle techniques performed by the physiotherapist. The components of the treatment include (a) pelvic floor muscle exercises using biofeedback (b) the use of vaginal dilators which are phallic-shaped silicone instruments (c) recommendations regarding sexual health (d) hands-on techniques such as pelvic floor massage and stretches (e) education (f) electrical stimulation and (g) home exercises. All participants in this treatment group will receive the same treatment approach, but treatment is flexible enough so that each participant will progress according to her own pace. In fact, you and your physiotherapist will discuss each step of the treatment to ensure that you will be in control of its progression. All participants in this group will receive nine physiotherapy sessions. If you still require physiotherapy beyond the length of the study, you will be referred to a different physiotherapist that specializes in pelvic floor physiotherapy for vulvar pain.

The treatments and the vaginal dilators will be provided to you free of charge. We ask that you avoid any other form of treatment for the PVD pain during the course of the study and until you have returned for a follow-up session. Within one month after you have completed the nine weeks of treatment you will return for a follow-up session. This follow-up session will include a gynecological exam at the Kingston General Hospital, an interview and questionnaire portion and sensory testing session done by the same researcher as prior to the treatment, and a pelvic floor muscle evaluation done by the physiotherapist. After completion of the follow-up session, you will be compensated \$50 for your participation in the study. You will be called approximately three months following the completion of the treatment sessions for a half-hour telephone interview with the psychology graduate student. The interview will include questions about your current pain levels and characteristics, sexual functioning, and satisfaction with the treatment. Do you have any questions? Are you interested in seeing if you are eligible for participating in the study? **(Note this on page 1 of the screening form)**

If no, thank them for their time, and ask them to feel free to call back if they change their mind. If yes, get their full name. Go through the questions on the screening form (pg. 2-4). If you come to a *(ineligible) explain why they are ineligible and thank them for their time. Ask them if they would like their name and contact information to be put into our recruitment database so we can contact them about future studies for which they may be eligible. Fill this out on the bottom slip of the Call Log page.

If they are eligible for the study: At this point you are eligible for the study. Are you still interested in participating? **(fill this in on form pg. 1)** **If yes,** we can now book you for the gynecological exam to ensure that you are eligible to participate in the entirety of the study. The entire study may take anywhere from 15 to 25 weeks, depending on scheduling. Will you be in Kingston for this length of time or be willing to come in for all sessions if you will be away? **(fill in timing info on form pg. 1)**

Obtain the participants contact information including at least one telephone number, the best time to call, and whether we can leave a message (we will only say that we are calling from Queen's University). Get an email address that they check regularly. Mark on the front page of the form that they are eligible to participate. Book the gynecological exam and note this date on the front page of the screening form. If schedules are such that the woman will be menstruating during the gynecological exam and she does not mind, that is fine. Let them know that the gynecological exam should not take more than 15 minutes however there may be a bit of waiting time before and they will need to fill out forms, so they should prepare to be there for at least 30 minutes. Let them know that someone will contact them a few days before the gynecological exam to let them know the details of where to go and what to bring.

We can also book you in for the interview and sensory session now, however remember that your participation is dependent on a positive diagnosis of PVD at the time of the gynecological examination. After the exam we will inform you about the gynecologist's diagnosis and will let you know whether or not you are able to participate in the study.

Book the interview/sensory testing session (book room for 3.5 hours but it should only take 2.5 hours. Book 30 minutes before and after for set-up and clean up. Need an RA from the 2-hour point) at a time when they are not menstruating and thank them again.

Enter all data into the Excel spreadsheet.

Reasons for ineligibility:

- under the age of 18 (for legal purposes)
- not fluent in English (need to fully understand the interview and questionnaire section)
- menopausal (likely has different etiological factors and therefore different treatment options)
- major medical or psychiatric conditions which impact with daily or sexual functioning (e.g. cancers, heart or other major organ problems, chronic fatigue syndrome, interstitial cystitis, incontinence) (these may confound the findings; we do not want to harm them any more)
- use of any medications (may alter pain processing system)
- another pain condition other than genital pain that significantly interferes with daily and sexual functioning (e.g. fibromyalgia, chronic back pain, chronic migraines) (vulvar pain may be a component of a larger pain disorder)
- genital pain other than PVD (e.g. GVD—pain all the time and everywhere on the vulva, pelvic or abdominal pain, vaginismus—spasms or avoidant behaviour which does not enable any penetration) (different etiological factors and therefore different treatment options)

- PVD for less than six months (may not be chronic)
- not willing to cease PVD treatment during study (can't control for effect of these treatments)
- never had a gynecological exam (our gynecologist cannot be the first to give the exam—no time to go through extensive education about the procedure)
- within six months post partum (pain may be due to birth process; do not want to harm body)
- breastfeeding or pregnant (don't want to do possible harm to woman and child)

Telephone Screening Form: Efficacy of Pelvic Floor Physiotherapy for Women with PVD

Date of Call: _____ **Method of Contact:** _____

Contacted Participant [1] OR Participant Contacted Us [2]

Name: _____

[1] [0]

Home #: () - **(best time to call:** **) leave a message? Y N**

Cell #: () - **(best time to call:** **) leave a message? Y N**

Work #: () - **(best time to call:** **) leave a message? Y N**

(Message will indicate that we are calling from Queen's University)

Email address: _____

Recruitment Source: _____

(location of poster if from a poster)

Interested in Finding out if they are Eligible? Y [1] N [0]

If no, any reason given? _____

Eligible for Study after Screening? Y [1] N [0] Not Sure (_____)

If no, why? _____

Interested in Participating? Y [1] N [0] If no, any reason given? _____

Availability _____

Gynecological Exam Date and Time: _____

(they can be menstruating if they don't mind)

Interview/Sensory Date and Time: _____

Eligible for Study after Gynecological Exam? Y [1] N [0]

If no, why? _____

It is okay to contact me for future studies in the lab!

Name: _____

Email Address: _____

Telephone Number: _____ You can leave a message? Y N

I am interested in online studies? Y N

I am interested in studies which involve coming into the lab? Y N

1. **Are you fluent in English? Y [1] N* [0]**

To determine if you are eligible to participate in the study we will need to ask you some questions about your medical history. Is that okay? Y [1] (→3) N [0]

If no, say "In order to determine whether you are eligible to participate we need to ask these questions. If you would like to think about it please take your time and call us back if you change your mind."

2. **How old are you?** _____ (* not eligible if under 18 or if menopausal; if over 45 ask if they are menopausal)

3. **Are you currently in a romantic or sexual relationship?** Y [1] N [0]

If yes, is this relationship heterosexual [1] or same-sex [0]? _____

4. **Are you currently suffering from any medical or psychiatric conditions?** Y*(if b or c are endorsed or condition is very serious) [1] N [0] (→6) (ask about incontinence)

If yes:

a) **With what condition(s) have you been diagnosed?** (If unsure of eligibility ask questions about how long they've had this diagnosis, severity of condition) _____

b) **Are you taking medication/receiving any treatment for this/these conditions?** Y* [1] N [0]

If yes, which one(s)? _____

c) **Does this condition interfere significantly with you daily and sexual functioning?** Y* [1] N [0]

5. **Have you ever suffered, or are you currently suffering, from a pain condition other than genital pain?** Y*(if d or e are endorsed or condition is very serious) [1] N [0] (→7)

If yes:

a) **With what condition(s) have you been diagnosed?** (same probes as above)

b) When did/do this episode/these episodes occur? _____

c) How long did/do this episode/these episodes last? _____

d) Are you currently taking painkillers/other treatment for this/these conditions? Y* [1]
N [0]

If yes, which one(s)? _____

e) Does this condition interfere significantly with your daily and sexual functioning? Y* [1]
N [0]

6. Do you currently experience pain in your genital region? Y [1] N* [0]

a) For how long have you had this pain? _____ (*not eligible if less than six months—tell them to call back if the pain persists for six months)

b) I am going to list some scenarios and let me know whether each reflects your experiences.

1. The genital pain is always or almost always present even in situations where pressure is not being applied Y* [1] N [0]

2. The genital pain occurs during sexual intercourse (penis, fingers, sex toys) Y [1]
N [0]

If yes, what percentage of intercourse attempts results in pain? _____

3. The genital pain occurs during tampon insertion Y [1] N [0] N/A (don't use tampons)

If yes, what percentage of these instances results in pain? _____

Does vaginal pain prevent tampon use? Y [1] N [0]

4. The genital pain occurs during gynecological exams Y [1] N [0]

If yes, do you experience pain at every gynecological exam? Y [1] N [0]

Does vaginal pain prevent gynecological exams? Y [1] N [0]

5. The genital pain is always or almost always present and worsens during intercourse or other activities involving vaginal penetration Y* [1] N [0]

6. Other _____

c) When does the pain start or worsen during these situations?

1. **Before the penis/object touches the vagina; it is always there** Y* [1] N [0]
2. **When the penis/object starts to enter the vagina** Y [1] N [0]
3. **When the penis/object is fully entered and thrusting** Y*(only if 2. not endorsed) [1] N [0]
4. **After penetration** Y*(only if 2. not endorsed) [1] N [0]

If yes, how long does it last? _____

d) From the following list, please indicate in which of these genital areas you feel the pain:

1. **At the vaginal opening** Y [1] N [0]
2. **Everywhere on the vulva** Y* [1] N [0]
3. **Inside the vagina** Y [1] N [0]
4. **In the pelvic or abdominal region** Y* [1] N [0]
5. **Another area** Y [1] N [0] _____

e) What adjectives would you use to describe the pain? _____

f) Have you received a diagnosis for this pain? Y [1] N [0]

If yes, what diagnosis/diagnoses did you receive? _____

By whom? _____

When? _____

g) Are you currently undergoing any treatment for the pain? Y [1] N [0]

If yes, which one(s)? _____

(* not eligible if currently undergoing physiotherapy)

Would you be willing to substitute this treatment for the duration of the study? Y [1] N* [0]

If no, have you ever undergone any treatment for the pain? Y [1] N [0]

If yes, which one(s)? _____ (* not eligible if they have had previous vestibular surgery)

7. **Do you have any difficulty with vaginal penetration other than the pain?** Y* (if spasms or avoidant behaviour that doesn't allow penetration) [1] N [0]

If yes, what? _____

8. **When was your last gynecological examination including a speculum examination?**

(* not eligible if they have never had a gynecological exam)

9. **Are you currently taking hormonal contraceptives?** Y [1] N [0]

10. **Do you have a regular menstrual cycle (approximately once a month)?** Y [1] N [0]

11. **What was the start date of your last period?** _____

12. **Have you ever given birth?** Y [1] N [0]

If yes, was this in the last six months? Y* [1] N [0]

How many vaginal deliveries have you had? _____

How many children have you had through caesarean-section? _____

Are you currently breastfeeding? Y* [1] N [0]

13. **Is there any possibility that you might currently be pregnant?** Y* [1] N [0]

2nd Gynecological Exam Date and Time: _____

(can be menstruating if they don't mind)

1 Month Follow-up Interview/Sensory Date and Time:

Telephone Screening Form: Controlled Study of Pelvic Floor Muscle Reactivity in Women with Provoked Vestibulodynia

Thank you for your interest in the study. Can I ask you where you found out about the study?

First I am going to tell you about the purpose of this study, as well as the details of what your participation would entail if you are eligible and choose to participate. This description and screening questionnaire could take 5 to 10 minutes, and some of the questions are personal in nature. Is now an appropriate time to complete the interview, or would you like us to give you a call back? [If to call back get their name and contact information and the best time to reach them]

Please interrupt me at any time if you have questions. The purpose of this study is to determine stress responses and reactivity patterns of the pelvic floor muscles (PFM) in healthy women. Your participation in the study would include 2 appointments. First, you would have a gynecological exam carried out at the Kingston General Hospital with a gynecologist, and a research assistant would be present in the room to record information. As Kingston General Hospital is a teaching hospital, it is also possible that a medical student will attend the gynecological exam. This appointment should take 30 minutes and will confirm the absence of vulvar pain and any other gynecological problems that would make you ineligible to participate.

After this, you will be contacted by the investigator to set-up an appointment at the Pelvic Floor Laboratory at the School of Rehabilitation Therapy at Queen's University. Testing will take place in a private room and a research assistant will be present throughout the experiment. This session will consist of a small interview, questionnaire, heart rate monitoring, and a pelvic floor evaluation using an electromyography system.

Before and after the pelvic floor muscle testing, you will be asked to answer some question on your past medical history, complete an anxiety questionnaire, and your heart rate will be monitored. The testing itself consists of a visual evaluation of your pelvic floor to ensure its normal functioning. The testing session will be performed in the regular gynecological position. The investigator will then set-up an electromyography system on your shoulder area, upper arm and at the level of your pelvic floor. The electromyography system allows the investigator to record information coming from your muscles. The pelvic floor set-up will consist of small electrodes placed close to the vaginal opening to record activity from your pelvic floor muscles, and a vaginal probe that will be inserted. Pressures will be applied at the base of your vaginal opening, similar to the "cotton-swab test" used by medical doctors to evaluate the vulva of women with vulvar pain. Every time a pressure is applied, the investigator will ask you to rate the intensity of pressure using a scale from 0 to 10. Although some pain may be experienced during this examination, no other health risks are posed, and the painful

sensations do not last for long periods of time. You are able to stop or to control the procedure at any time. To compensate you for your time and participation you will be reimbursed 20\$.

Do you have any questions? Are you interested in seeing if you are eligible for participating in the study? NO → *thank them for their time, and ask them to feel free to call back if they change their mind.*

YES → *get their full name. Go through the questions on the screening form. If you come to a *(ineligible) explain why they are ineligible and thank them for their time.*

1. **Fluent in English** (*if obvious: do not ask!*) Y [1] N* [0]

2. **To determine if you are eligible to participate in the study we will need to ask you some questions about your medical history. Is that okay?** Y [1] (→3) N [0]

If no, say “In order to determine whether you are eligible to participate we need to ask these questions. If you would like to think about it please take your time and call us back if you change your mind.”

3. **How old are you?** _____ (** not eligible if under 18 or if menopausal*)

4. **Are you currently in a romantic or sexual relationship?**

Y [1] N [0]

If yes, is this relationship heterosexual [1] or same-sex [0] or other [2]? _____

5. **Are you currently suffering from any medical or psychiatric conditions?**

Y* (*if b or c are endorsed or condition is very serious*) [1] N [0] (→6)

a) If YES With what condition(s) have you been diagnosed? (*If unsure of eligibility ask questions about how long they've had this diagnosis, severity of condition, etc*)

b) Are you taking medication/receiving any treatment for this/these conditions?

Y* [1] N [0]

If YES, which one(s)? _____

c) Does this condition interfere significantly with your daily and sexual functioning?

Y* [1] **N** [0]

6. Have you ever suffered, or are you currently suffering, from a pain condition other than genital pain? Y* (if d or e are endorsed or condition is very serious) [1] **N** [0] (→7)

a) If YES With what condition(s) have you been diagnosed? (same probes as above)

b) When did/do this episode/these episodes occur? _____

c) How long did/do this episode/these episodes last? _____

d) Are you currently taking painkillers/other treatment for this/these conditions?

Y* [1] **N** [0]

If yes, which one(s)? _____

e) Does this condition interfere significantly with your daily and sexual functioning?

Y* [1] **N** [0]

7. Do you currently experience pain in your genital region?

Y* [1] **N** [0]

For how long have you had this pain? _____ (*not eligible if the pain has persisted for ≥ six months; if they do, please screen for eligibility in Corrie's physio study)

If less than 6 month: how frequently do you experience the vulvar pain? _____

(*not eligible if more than 25% of penetrative activities)

8. Do you have any difficulty with vaginal penetration? (e.g. spasm, fear, avoidant behaviour)

Y* [1] **N** [0]

9. When was your last gynecological examination including a speculum examination?

_____ (* not eligible if they have never had a gynecological exam)

10. **Are you currently taking hormonal contraceptives?** Y [1] N [0]

11. **Do you have a regular menstrual cycle (approximately once a month)?** Y [1] N [0]

12. **What was the start date of your last period?** _____

13. **Have you ever given birth?** Y* [1] N [0]

14. **Is there any possibility that you might currently be pregnant?** Y* [1] N [0]

At this point: 1. Give the participant an ID number using the PFM Study database

2. Book the Gyne exam and write down info on contact sheet

3. If possible, also book the Pelvic Floor Exam Session

Are they eligible? Y[1] N [0]

YES → *At this point you are eligible for the study. Are you still interested in participating?*

NO → Explain why, thank them, and ask them if they want to participate in other studies

NO → *Thank them for their participation and ask if they would be interested to participate in other studies in the lab, and make sure you have their contact info on contact sheet.*

YES → *We can now book their gynecological exam.*

Remember that your participation is dependent on a negative diagnosis of vulvar pain at the time of the gynecological examination. After the exam we will inform you about the gynecologist's diagnosis and will let you know whether or not you are able to participate in the study.

Would you be interested in participating in other studies in the lab?

Enter data in Excel spreadsheet.

Appendix D Information and Consent Forms



Letter of Information and Consent Form

The effectiveness of pelvic floor physiotherapy in women with provoked vestibulodynia

Investigators:

Caroline Pukall, Ph.D., Assistant Professor, Department of Psychology, Queen's University; Corrie Goldfinger, B.A. M.A Candidate, Department of Psychology, Queen's University; Linda McLean, P.T., Ph.D., Assistant Professor, School of Rehabilitation Therapy, Queen's University; Evelyne Gentilcore-Saulnier, B.Sc., M.Sc. Candidate, School of Rehabilitation Therapy, Queen's University; Susan Chamberlain, M.D., Assistant Professor, Department of Obstetrics and Gynecology, Queen's University

Background Information: You are being invited to participate in a research study directed by a multidisciplinary treatment team consisting of psychologists, physiotherapists, and a gynecologist to evaluate the effectiveness of pelvic floor physiotherapy for women with provoked vestibulodynia (PVD; previously called vulvar vestibulitis syndrome or VVS), a common cause of painful intercourse. The psychology graduate student will read through this consent form with you, describe the procedures in detail, and answer any questions you may have. This study has been reviewed for ethical compliance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

There is currently no single treatment that has been shown to be effective for all women with PVD. Research has indicated that increased pelvic floor muscle tension plays a role in maintaining and worsening the pain in women with PVD. Although some research has shown positive results after using one of the techniques commonly used in pelvic floor physiotherapy (i.e., biofeedback), and one self-report study demonstrated some success with pelvic floor physiotherapy, there have been no studies assessing pain and other important variables (e.g., sexual function) before and after a standardized pelvic floor physiotherapy protocol.

Purpose of the Study: The purpose of the study is to conduct a preliminary investigation to determine the effectiveness of pelvic floor physiotherapy in reducing pain and improving psychosexual functioning and pelvic floor muscle physiological variables in women with PVD.

Inclusion and Exclusion Criteria: You will be considered for this study if you meet the following criteria: 1) over the age of 18 and premenopausal; 2) receive a diagnosis of PVD from the study gynecologist; 3) have experienced the vulvar pain for a minimum of six months, and 4) able to undergo a physical examination by a gynecologist. You will not be considered for this study if you meet any of the following criteria: 1) are currently using any other treatments for PVD and/or are not willing to refrain from using other treatments for PVD for the entirety of the present study; 2) have

any major medical, psychiatric, or other pain conditions that significantly interfere with your daily or sexual functioning; 3) are taking any medications that may interfere with pain processing (e.g., antidepressant medication); 4) are pregnant, breastfeeding, or have given birth within the last six months, or 5) have had genital surgery. If your status with respect to any of these has changed since your initial telephone screening and you believe that you may no longer be eligible to participate, please let the graduate student know.

Procedures of the Study: Your participation in the study involves undergoing the following procedures: 1) a gynecological examination; 2) a semi-structured interview and questionnaires and brief sensory testing session; 3) one physiotherapy pelvic floor evaluation, 4) nine weekly treatment sessions of pelvic floor physiotherapy, 5) a 1-month follow-up session, and 6) a 3-month follow-up telephone interview.

Gynecological examination: During the gynecological examination (10-15 minutes), the gynecologist will examine the internal and external genitalia and reproductive organs, and palpate external genital areas with a cotton-swab while asking you to rate the intensity of the pain on a scale from 0 to 10. You will be in control of the procedure and may ask to stop or slow down at any time. The graduate student will be present during the examination to record information. If your diagnosis is not consistent with PVD, or if you cannot complete all aspects of the gynecological examination, you will not be eligible to participate in the remainder of the study. In this case, the graduate student will explain to you why you are not eligible and can provide you with some information about vulvar health if you wish. Please note that although the gynecologist will be seeing you for the examination, a file will not be created for you at KGH and no ongoing gynecologic care will be provided. The gynecologist's role is strictly that of diagnosis for the purpose of inclusion into the research study.

Interview, questionnaires, and sensory testing: The semi-structured interview and questionnaires will take place at the Sexual Health Research Lab (SHRL) at the Department of Psychology, Queen's University with a graduate student (1.5-2 hours). Questions will cover demographic information, medical and gynecological history, pain during sexual intercourse and other activities, sexual and relationship history, and current physical and psychological symptoms. Following the completion of these, you will complete a brief (20 minute) sensory testing session in which the graduate student will measure your pressure pain thresholds. You will be presented with varying intensities over your forearm first, and then the 6 o'clock (i.e., posterior) position of the vulvar vestibule (i.e., the area of skin around the entrance to your vagina) using a cotton swab attached to a device that exerts set amounts of pressure. You will be presented with a range of weak and strong pressures and will be asked to rate them on intensity and unpleasantness scales from 0 to 10. The pressure stimuli increase in small increments. We do not increase pressure to any standard amount for all participants, so the amount of increase will depend entirely on your ratings. Although some of the stimuli may be uncomfortable or painful, they will not damage your skin. You will be in control of the procedure and may ask to stop or slow down at any time. You can withdraw from and/or terminate any stimulus that is too uncomfortable at any time.

Treatment: The pelvic floor physiotherapy evaluation, which all participants will complete, will be performed by a physiotherapist at the Queen's University Motor Performance Laboratory. The

physiotherapy evaluation will consist of an interview of your medical history, a pelvic floor physical examination and an educational session (1.5-2 hours). Her questions may be similar to the ones asked during the interview session. They will cover your medical history with respect to PVD, your description of your pain during sexual intercourse, your urinary voiding habits and other current physical symptoms. She will also explain to you the details of the pelvic floor evaluation, which will be performed in a gynecological position. The physiotherapist will then record your heart rate and blood pressure to measure your level of stress before the procedures. During the evaluation, the physiotherapist will visually and manually evaluate your pelvic floor muscles both externally and internally. This will be done in order to evaluate its capacity to contract and relax. The physical examination will also consist of a biofeedback (electromyography) test during which you will be asked to insert a small probe in your vagina. The therapist will visually inspect the probe to ensure that it is properly located, and then the probe will be used to allow the therapist to record the reaction of your pelvic floor muscles to different stimuli including light touch and pressure applied to your genitals. A female research assistant will be present during the evaluation to record information. After the physical evaluation, the physiotherapist will discuss with you the results of the evaluation, and finally, provide answers to any questions or concerns you might have.

At this point, you will set up a weekly meeting time with the physiotherapist for treatment sessions. You will complete nine 1-hour weekly pelvic floor physiotherapy treatment sessions. After completion of the physiotherapy evaluation, you and the physiotherapist will discuss your treatment goals, the treatment techniques and the expected results. You will be provided with home exercises, which will change as the treatment progresses. Each session will be tailored to your progress and to the findings on your initial physiotherapy assessment. They will consist of manual intra-vaginal techniques such as pelvic floor muscle massage and stretches, pelvic floor muscle retraining using biofeedback, training with vaginal dilators, recommendations regarding sexual health, and a series of related exercises for you to carry out at home. All participants in this treatment group will receive the same information and education. The treatment will be progressed based on your symptoms, which means that the treatment is flexible and allows each participant to progress according to their own pace. In fact, you and your physiotherapist will discuss each step of the treatment, and you will be in control of your treatment progression. Should you still require physiotherapy beyond the length of the study, you will be referred to another physiotherapist that specializes in pelvic floor physiotherapy.

Follow-up sessions: Approximately one month after the completion of the pelvic floor physiotherapy, the gynecological examination, interview and questionnaires, sensory testing, and pelvic floor physiotherapy evaluation will be repeated to assess the short-term effects of the treatment on pain and other symptoms. To assess long-term effects of the treatment, you will be called approximately three months following the completion of the treatment sessions for a half-hour telephone interview with the psychology graduate student. The interview will include questions about your current pain levels and characteristics, sexual functioning, and satisfaction with the treatment.

Compensation: All treatment will be provided free of charge and you will be provided with a set of dilators that are yours to keep after the completion of the study. You will be given \$50 at the completion of the 1-month follow-up session to compensate you for the time and inconvenience related to the multiple appointments required by this study.

Risks and Benefits: It is possible that you may experience some discomfort or pain due to some of the procedures (i.e., gynecological examination, sensory testing, pelvic floor physiotherapy treatment sessions). Some of the issues discussed in the interview may be considered sensitive (e.g., sexuality, depression) and therefore may cause some distress. Pelvic floor physiotherapy can also cause a temporary increase in pelvic floor muscle soreness as a result of the treatment techniques. The direct potential benefits include: access to a multidisciplinary treatment team comprised of psychologists and physiotherapists; education about pelvic floor function, pain, and sexual function; and a greater understanding of the cycle of pain. You may also experience a reduction in vulvar pain and/or improvements in psychosocial variables related pain reduction (e.g., improved sexual functioning, improved quality of life) after the treatment. The indirect benefit of your participation is that clinicians will have a better understanding of the usefulness of pelvic floor physiotherapy as a treatment for women with PVD; this information may benefit other women in the future.

Confidentiality: All information obtained during the course of this study is strictly confidential and your anonymity will be protected at all times. A hard copy of your interview, questionnaires, gynecological examination, and physiotherapy notes will be kept in a filing cabinet in a locked office. Electronic copies of some of your questionnaires will be kept in a password-protected file in the same locked office. All of these forms and files identify you only by a participant ID number rather than your name, and the electronic file which matches up participant names and ID numbers is password-protected. The results of the interview and questionnaires, and the physiotherapy sessions will be available only to the investigators directly involved in this study, as well as research assistants at the SHRL who are required to sign a confidentiality form. Neither your name nor any other identifying information will be mentioned in any publications or reports.

Participant Rights and Liability: Your participation in this study is voluntary. You may withdraw from this study at any time and your withdrawal will not affect your future access to services. You are also free to refuse to answer any questions posed without explanation. The study investigators may decide to withdraw you from this study for scientific reasons at any time during the study. In this case, you will be informed of the reason for withdrawal. In the event that you are injured as a result of the study procedures, medical care will be provided to you until resolution of the medical problem. By signing this consent form, you do not waive your legal rights nor release the investigators from their legal and professional responsibilities.

Participant's Signature: I have read and understood the consent form for this study, I have had the purposes and procedures of this study explained to me. I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form. I will receive a copy of this consent form for my information.

If at any time I have further questions, problems, of adverse events, I can contact:

Study Investigators: Faculty Supervisors: Caroline Pukall, Ph.D. at (613) 553-3200 or caroline.pukall@queensu.ca Linda McLean, PT, Ph.D. at (613) 533-6101 or mcleanl@post.queensu.ca

Graduate Students: Corrie Goldfinger at (613) 533-3276 or 5cg24@queensu.ca Evelyne Gentilcore-Saulnier at (613) 533-6000 extension 77850 or 5eg11@queensu.ca

Department of Psychology, Head: Vern Quinsey, Ph.D. at (613) 533-2492 or psyhead@post.queensu.ca

If I have questions regarding my rights as a research subject I can contact:

Dr. Albert Clark, Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board at (613) 533-6081

By signing this consent form, I am indicating that I agree to participate in this study.

Signature of Participant Print Name Date

Statement of Investigator: I have carefully explained to the participant the nature of the above research study. I certify that, to the best of my knowledge, the participant understands clearly the nature of the study and demands, benefits, and risks involved to participants in this study.

Signature of Investigator Print Name Date



Letter of Information and Consent Form

Controlled Study of Pelvic Floor Muscle Reactivity in Women with Provoked Vestibulodyni

Investigators

Evelyne Gentilcore-Saulnier, B.Sc., M.Sc. Candidate, School of Rehabilitation Therapy; Corrie Goldfinger, B.A. M.A. Candidate, Department of Psychology; Linda McLean, P.T., Ph.D., Associate Professor, School of Rehabilitation Therapy; Caroline Pukall, Ph.D., Assistant Professor, Department of Psychology; Sue Chamberlain, M.D., Assistant Professor, Department of Obstetrics and Gynecology

Background Information

You have been invited to participate in a research project directed by Drs. Linda McLean and Caroline Pukall to evaluate physiological and psychological stress responses as well as pelvic floor muscles' response to a pressure stimulus applied at the vulvar vestibule. The research investigator will read this consent form with you, describe procedures in detail, and answer any questions that you may have. This study has been reviewed for ethical compliance by the Queen's University Health Sciences Research Ethics Board.

Purpose of the Study

The purpose of the study is to conduct a preliminary investigation of stress responses and pelvic floor muscle responses in women with and without vulvar pain.

Inclusion and Exclusion Criteria

You will be considered for this study if you meet the following criteria: a) have no history of chronic vulvar pain, b) are 18 years of age or older and who are premenopausal and c) have never given birth to a child. You will not be considered eligible for the project if you: a) have a major medical, psychiatric, or other pain conditions that interfere with your daily or sexual functioning (including vulvodynia, vaginismus, and pelvic pain).

Procedures of the Study

If you agree to participate in this study you will be asked to undergo one 15-20 minutes gynecological examination at the Kingston General Hospital (KGH) and one 60-90 minute pelvic floor muscle evaluation. Testing will take place in a private room, at the Pelvic Floor Laboratory at the School of Rehabilitation Therapy, Queen's University. Please note that a research assistant will be present throughout the experiment to record information at both session.

1. Gynecological examination: The investigator will read with you the present consent form before the examination. During the gynecological examination the gynecologist will examine the internal and external genitalia and reproductive organs, and palpate external genital areas with a cotton-swab while asking you to rate the intensity of the pain on a scale from 0 to 10. You will be in control of the procedure and may ask to stop or slow down at any time. The graduate student will be present during the examination to record information. If your diagnosis is not consistent with PVD, or if you cannot complete all aspects of the gynecological examination, you will not be eligible to participate in the remainder of the study. In this case, the graduate student will explain

to you why you are not eligible and can provide you with some information about vulvar health if you wish. Please note that although the gynecologist will be seeing you for the examination, a file will not be created for you at KGH and no ongoing gynecologic care will be provided. The gynecologist's role is strictly that of diagnosis for the purpose of inclusion into the research study.

2. Pelvic floor muscle evaluation: The investigator will review a second time this consent form with you, ask questions about some demographic and past medical history information, and address your questions and concerns. You will be given verbal instructions by the investigator on how to complete an anxiety questionnaire. You will be instructed to undress from the hips down, and will be left alone in the room to do so. Activity from your left trapezius and left bicep muscles will be recorded using an electromyography system, which consists of two electrodes placed over clean and dry skin. The electromyography system allows the investigator to record information coming from your muscles. Then, you will be asked to get in the testing position, which consists of a common gynecological testing position. Your heart rate will then be monitored over a 3-minute period. The investigator will perform a visual and manual evaluation of your pelvic floor by asking you to cough and then contract your pelvic floor muscles. This examination will be done to ensure normal functioning of your pelvic floor muscles.

The investigator will then set up an electromyography system at the level of your pelvic floor. The testing session will be performed in the regular gynecological position. The pelvic floor set-up will consist of small electrodes placed between the labia minora and labia majora close to the vaginal opening to record activity from your pelvic floor muscles. Next, the investigator will ask you to insert a probe into your vagina and will leave you alone in the room to do so. The probe also records activity coming from your pelvic floor muscles. If you require assistance inserting the probe, the investigator will be available to you at any time. You may remove the probe and abandon the session at any time without justification or negative consequence.

At this point, we will be ready to record information coming from your pelvic floor and upper limb muscles in reaction to a pressure stimulus. The pressure stimulus will be delivered at the entrance of your vagina using a tool called a "vulvalgesiometer". A demonstration of the vulvalgesiometer (i.e. a cotton swab attached to a device that exerts set amounts of pressure) will be performed over your thigh before any pressure is applied at the vulva so that you will know what to expect during the test. Four pressures will be applied 3 times each at the 6 o'clock location (i.e., base) of the vaginal opening (please refer to attached figure). None of the stimuli will be applied internally, and you will be given 60-second of rest between each application. The pressure stimuli will be increased in small increments, and you will be asked to rate them on touch and pain intensity using a scale from 0 to 10. Pressures will be applied until you indicate that you feel a pain of 6 on the scale, at which point two more pressure applications at that same level will be applied with no further increase in the amount of pressure delivered. This will indicate the end of the electromyography testing.

After the testing session, the investigator will provide answers to any questions or concerns you might have, give you a debriefing sheet, and provide you with information on vulvar pain conditions and pelvic floor muscle functioning. Lastly, before you leave the testing room, the investigator will ask that you complete a second anxiety questionnaire and will record your heart rate over a second 3-minute period.

Alternative Therapies

You will not receive any form of treatment through participating in this study. The researcher will educate you on pelvic floor muscles and vulvar pain.

Confidentiality

All information obtained during the course of this study is strictly confidential and your anonymity will be protected at all times. You will be identified by a participant number only, not your name. Data will be stored in locked files at the Pelvic Floor Laboratory and will be available only to the investigators. Only the principal investigators will have access to your name and contact information. Any use of your data for teaching purposes, publications or reports will not reveal your identity.

Voluntary nature of study/Freedom to withdraw or participate

Your participation in this study is voluntary. You may withdraw from this study at any time and your withdrawal will not affect your future medical care with any physician, physiotherapist or nurse at any hospital or clinic. You are also free to refuse to answer any questions posed.

Withdrawal of subject by principle investigator

The investigators may decide to withdraw you from this study for scientific reasons at any time during the study. In this case, you will be informed of the reason for withdrawal.

Risks and Benefits

While you may not benefit directly from this study, results from this study will set grounds for a greater study looking at the pelvic floor muscles reaction in women with and without vulvar pain. This will then contribute to our ability to improve the understanding of how the muscles of the pelvic floor function under normal circumstances and how they are affected in women with vulvar pain. This information may benefit future patients by allowing us to design optimal treatment programs. By participating in this project, you will receive information about pelvic floor function, vulvar pain and sexual function. It is possible that you experience some discomfort or pain due the procedures. Discomfort will be temporary, and no tissue damage will occur as a cause of the testing.

Liability

In the event that you are injured as a result of taking part in this study, medical care will be provided to you until resolution of the medical problem. By signing this consent form, you do not waive your legal rights nor release the investigator(s) and sponsor from their legal and professional responsibilities.

Payment

A \$20 compensation is offered for your participation in this study.

SUBJECT STATEMENT AND SIGNATURE SECTION:

I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form. I will receive a copy of this consent form for my information.

If at any time I have further questions, problems or adverse events, I can contact

Dr. Linda McLean (Principal Investigator) at (613) 533-6101

or

Dr. Elsie Culham (Department Head) at (613) 533-6727

If I have questions regarding my rights as a research subject I can contact

Dr. Albert Clark, Chair, Research Ethics Board at (613) 533-6081

By signing this consent form, I am indicating that I agree to participate in this study.

Volunteer Signature Date

Witness Signature Date

I would be interested in participating in future studies conducted by the Motor Performance Pelvic Floor Muscle Lab and/or the Sexual Health Research Lab. I would like to receive information on the study findings, when available at the following email address:

STATEMENT OF INVESTIGATOR:

I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I clarify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved in participating in this study.

Principal Investigator Date

Appendix E Confidentiality Form



Information about Confidentiality Sexual Health Research Lab 62 Arch Street,
Kingston, Ontario K7L 3N6 Email: SHRL@queensu.ca Phone: (613) 533-3276

All information disclosed during your participation in this research study is confidential and **will not** be disclosed to anyone without your written and informed consent **except** where reporting is required by law, that is –

1. where there is suspicion that a child or children (that is, an individual who is PRESENTLY under the age of 16) has been or is being abused,
2. where the research participant is likely to harm herself or himself unless protective measures are taken,
3. where the research participant presents a serious danger of violence to others, and
4. if the research participant reveals that she has been sexually abused by a health care provider (for example, a psychologist or physician) covered by the Regulated Health Professionals Act, it is necessary by law to report the name of the perpetrator to his/her governing body.

IF YOU HAVE ANY CONCERNS ABOUT THESE MATTERS, OR ABOUT THIS FORM,
PLEASE DISCUSS THESE WITH ME.

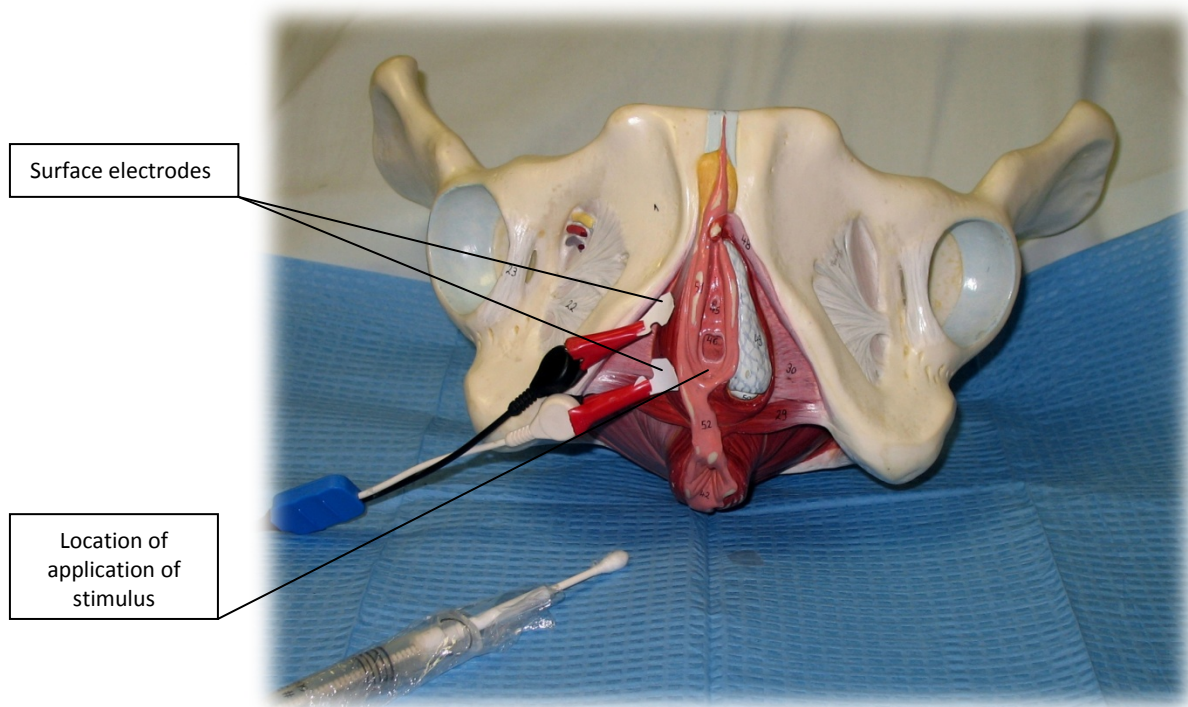
PLEASE SIGN THE ACKNOWLEDGEMENT BELOW TO INDICATE THAT YOU HAVE READ THIS
INFORMATION ABOUT CONFIDENTIALITY

I acknowledge the circumstances that limit confidentiality and I accept them.

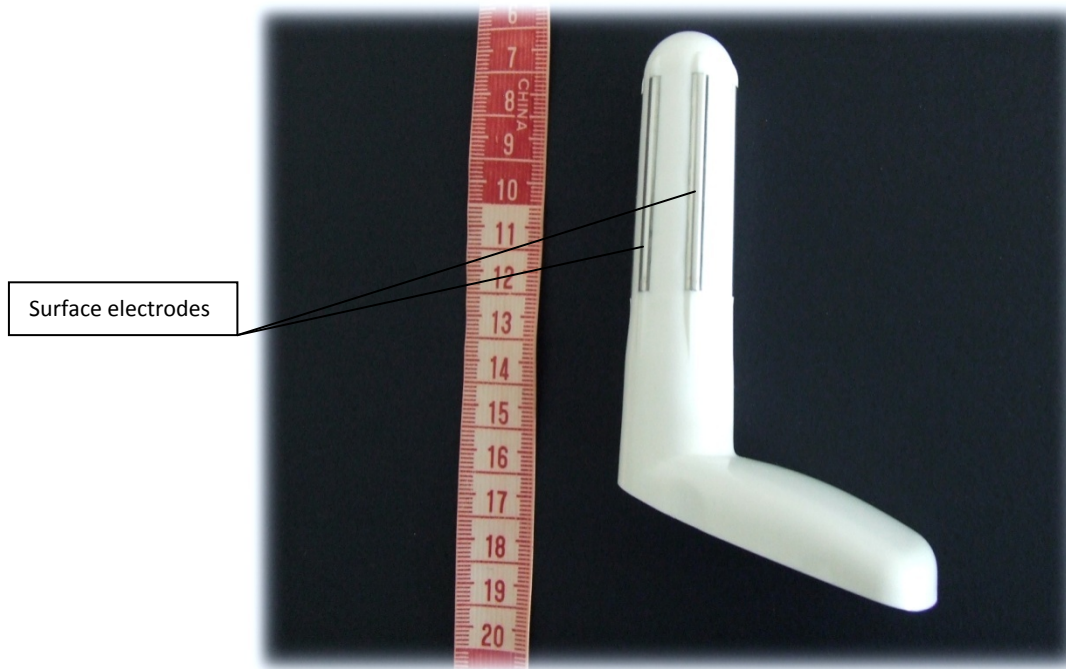
Participant's name Participant's signature Date

Witness' name Witness' signature Date

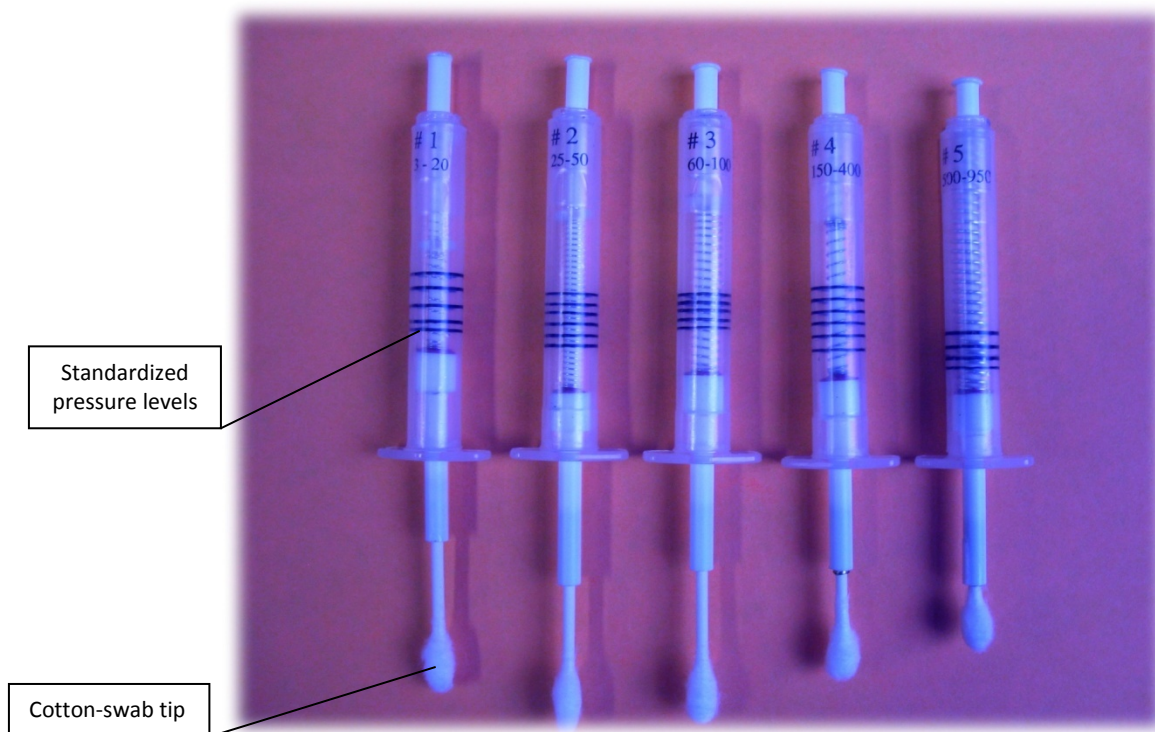
Appendix F EMG Set-up of the Superficial PFMs



Appendix G Femiscan™ Probe



Appendix H Vulvalgesiometer Set



Appendix I Testing Protocol

Introduction: Introduce the RA and the investigator to the participant. Go through the consent form with the participant. Explain the testing session sequence

ID number: _____

1. EVALUATION * = not eligible to participate

Evaluating physiotherapist: _____

Date: _____ **Time:** _____

Birth date: _____ **Age:** _____ **Sex:** F / M*

Pacemaker Y*/ N **Height:** _____ **Weight:** _____

Smoker: Y / N

Occupational status: Employed FT / PT / Unemployed / Student/ Other _____

Marital status: Single/ In a relationship/ Living with a partner/ Married

SECTION I: Medical history

Past medical history and associated conditions: Repetitive yeast infections in the past? Y / N

of UTI(s) over the last year: _____ # of vaginal infection(s) over the last year: _____

STIs? _____ **Allergies?** _____

Others medical/musculoskeletal conditions: (migraines, etc.)

Current* and past medications (if applicable):

Menstrual cycle: regular / irregular **PAINFUL every month? Y / N If not, how often?**

Onset of menarche (age)? _____ H.C.? Y / N Onset (age)? _____

How many days since 1st day of last menstruation? _____

Perceived physical activity level? Please circle: High, Moderate, Low. *Please describe:*

SECTION II : VOIDING HABITS

Urine: Frequency: _____ /day

Frequency: _____ /night

Conditions	Y	N
Urge incontinence		
Stress incontinence		
Can voluntary stop urine flow		
Other(s):		

Bowel: Frequency: _____ / __day(s)

Conditions	Y	N
Urgency		
Constipation		
Incontinence		
Other(s):		

Do you have any questions or concerns before we start the physical evaluation? Details

Participant is left alone to take underwear out and get in a gynaecological testing position and use a cover sheet for discretion (*back supported by pillows, feet in feet rests, strap around the knees*).

4. VISUAL PFM AND VULVAR INSPECTION (check when applicable)

Vestibule:

Scar *Where:* No abnormalities

Erythema *Where:* Fissure *Where:*

Pelvic floor response when asked to perform a voluntary contraction:

No visible contraction Mild contraction Good contraction

Compensations Inverse command *Note:*

Pelvic floor response to coughing:

Contraction No response Descent

- ✓ Set up superficial electrodes at the PFMs.

5. EMG TESTING

1. 10s **REST**
2. 5s **Sub-max TEST contractions**
 - Rep 1 Rep 2 Rep 3
 - MVC** Rep 4 : PAIN RATING: /10
3. 10s **Sensory testing** at 6 o'clock – **30-90s ISI**

A. Pressure for **light T: 10g (#1)**

- Rep 1
- Rep 2
- Rep 3
- Rep 4: BLANK TRIAL
- Rep 5: BLANK TRIAL perineum pressure

B. Pressure for **T or P: 25g (#2)**

- Rep 1
- Rep 2
- Rep 3

C. Pressure for **above P: 60g (#3)**

- Rep 1 pressure:_____
- Rep 2 pressure:_____
- Rep 3 pressure:_____
- Rep 4 pressure:_____
- Rep 5 pressure:_____
- Rep 6 pressure:_____
- Rep 7 pressure:_____
- Rep 8 pressure:_____
- Rep 9 pressure:_____
- Rep 10 pressure:_____

o D. Pressure for controls **above P: ≥200g(#5)**

- Rep 1 pressure:_____
- Rep 2 pressure:_____
- Rep 3 pressure:_____
- Rep 4 pressure:_____
- Rep 5 pressure:_____
- Rep 6 pressure:_____
- Rep 7 pressure:_____
- Rep 8 pressure:_____
- Rep 9 pressure:_____
- Rep 10 pressure:_____

Pain levels on a 0-10 VAS:

A. (circle: N / T / P)

- /10 N/T / P
- /10 N/ T / P
- /10 N / T / P

B. (circle: T / P)

- /10 T / P
- /10 T / P
- /10 T / P

C. (circle: T / P)

- 1 /10 T / P
- 2 /10 T / P
- 3 /10 T / P
- 4 /10 T / P
- 5 /10 T / P
- 6 /10 T / P
- 7 /10 T / P
- 8 /10 T / P
- 9 /10 T / P
- 10 /10 T / P

o D.. (circle: T / P)

- 1 /10 T / P
- 2 /10 T / P
- 3 /10 T / P
- 4 /10 T / P
- 5 /10 T / P
- 6 /10 T / P
- 7 /10 T / P
- 8 /10 T / P
- 9 /10 T / P
- 10 /10 T / P

Please describe the pain you felt during the application of the pressures?

7. Un-do set-up

- ✓ Remove probe and surface EMG electrodes with the assistance of the physiotherapist.
- ✓ In the event of vulvar discomfort, cold water in a towel will be provided for the participant to use as needed.

Appendix J Debriefing Sheet

Controlled Study of Pelvic Floor Muscle Reactivity upon a Provoked Vulvar Pain

You have been invited to participate in this study because you have no history of chronic vulvar pain, are 18 years of age or older, premenopausal and nulliparous. The purpose of the study was to conduct a preliminary investigation of stress and pelvic floor muscles (PFM) responses to a pressure stimulus at the vulvar vestibule in women with and without provoked vestibulodynia (PVD), a form of chronic vulvar pain. We were also interested in examining the psychological and physiological stress in anticipation of a pelvic floor examination among women with and without PVD. This study was conducted for educational purposes. We recruited two main groups of participants: women with PVD and women without such pain. Participants were recruited via letters sent to local doctor's offices and advertisements. All participation was voluntary.

Research conducted with women with PVD has noted an association between vulvar pain and PFM. It has been suggested that PFM dysfunction is a contributor to the pain in PVD (Reissing, 2005). Studies looking at the effectiveness of interventions directed towards rehabilitation of the PFM (Bergeron, 2002) have proven successful in relieving pain associated with PVD. However, studies investigating the nature of the relationship between the PFMs and PVD are missing (Zolnoun, 2006). For example, it is suspected that a woman's pelvic floor muscle contracts in response to provoked vulvar pain, however research has neglected to assess this aspect. Clinically, understanding the role of the PFMs in the etiology of PVD has strong implications for current physical therapy treatment, since the focus of treatment is the PFMs. One of the aims of the present study was to advance understanding and stimulate research on PFMs in women with and without vulvar pain.

As stated previously, all information that you provided throughout the study is confidential. The research team members working directly on this project are the only individuals who have access to your responses. As compensation for your participation, you will be sent a cheque for \$20.00 to your home address.

Thank you for your participation in this study. It is greatly appreciated! Should you have any further questions, comments or concerns, please do not hesitate to contact the Pelvic Floor Laboratory at (613)537-9009, the Sexual Health Research Laboratory at (613) 533-3276, or SHRL@queensu.ca, Dr Linda McLean at (613)533-6101 or Dr Caroline Pukall at (613) 533-3200. If you would like further information regarding this research topic or related topics, please consult the following articles:

- 1. Bergeron, S., Binik, Y. M., Khalifé, S., Pagidas, K., Glazer, H. I., Meana, M., et al. (2001). A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis. *Pain*, 91(3), 297-306.**
- 2. Reissing, E. D., Brown, C., Lord, M. J., Binik, Y. M., & Khalifé, S. (2005). Pelvic floor muscle functioning in women with vulvar vestibulitis syndrome. *Journal of Psychosomatic Obstetrics and Gynaecology*, 26(2), 107-113.**

3. Zolnoun, D., Hartmann, K., Lamvu, G., As-Sanie, S., Maixner, W., & Steege, J. (2006). A conceptual model for the pathophysiology of vulvar vestibulitis syndrome. *Obstetrical & Gynecological Survey*, 61(6), 395-401.

Below is some more general information on vulvar pain (vulvodynia) and associated treatment as well as information on the pelvic floor muscles. Who knows? You may use this information in the future to inform a close friend experiencing vulvar pain.

What is Vulvodynia?

Vulvodynia is defined as “vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable, neurologic disorder.” Vulvodynia affects an estimated 16% of women in the general population. There are two major types of vulvodynia that are based on pain location. The first is LOCALIZED vulvodynia, in which pain is restricted to a portion of the vulva, such as the vestibule (i.e., the entrance of the vagina), as in provoked vestibulodynia (PVD), known previously as vulvar vestibulitis syndrome (VVS). The second is GENERALIZED vulvodynia (GVD), in which the pain is more diffuse, involving the whole vulva.

What is Provoked Vestibulodynia (PVD)?

PVD is the most common cause of dyspareunia (i.e., painful intercourse) in women of child-bearing age. A recent epidemiological study estimated that PVD affects 12% of pre-menopausal women in the general population. Women with PVD report experiencing a highly localized, burning and/or cutting pain at the vulvar vestibule during sexual intercourse, as well as during other activities that involve applying pressure to the vestibule (e.g., tampon insertion, gynecological exams). Although the pain of PVD typically disappears after pressure to the vestibule is removed, many women report lasting pain or discomfort after sexual intercourse or similar activities.

Approximately 50% of women who suffer from PVD have what is called PRIMARY PVD, indicating that the pain has been present since their first intercourse attempt. The other half has SECONDARY OR ACQUIRED PVD, which develops after a period of pain-free intercourse, and in many cases, after an aggravating factor (e.g., repeated vaginal infections, sexually transmitted diseases). However, little is known about the causes of PVD; most health professionals agree that it is caused by a combination of factors.

How is PVD Treated?

There is scientific evidence that the following treatments are effective for PVD: First, psychotherapy including a specific focus on pain management and sexuality. This can be done in group, couple, or individual format. Second, pelvic floor muscle training/physiotherapy assisted by biofeedback. Lastly, surgical removal of the painful area of the vulvar vestibule, called vestibulectomy.

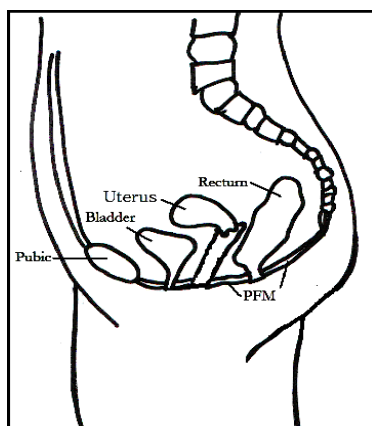
It is generally recommended to begin treatment with either psychotherapy or physiotherapy, or both. Psychotherapy and pelvic floor muscle training via biofeedback are equally successful; both treatments complement each other well. Thirty-five to forty percent of women who followed either of these treatments reported a great decrease in their pain or complete pain relief, as reported in a treatment outcome study published in the journal PAIN in 2001. As well, another published study indicated that 70% of women who underwent an average of 7 sessions of pelvic floor physiotherapy reported moderate or great improvement in their pain and sexual functioning.

If there is no significant improvement with psychotherapy or physiotherapy, a vestibulectomy may be indicated. This is a relatively minor day procedure carried out under general or spinal anesthesia. Following the operation, women will typically experience some discomfort in the genital region. Neither intercourse nor any other penetrative activity should be attempted for 6-8 weeks post-surgery. Seventy percent of women who underwent this surgery reported a great decrease in their pain or complete pain relief in the treatment outcome study mentioned above.

You may come across information about other forms of treatment for PVD, such as vaginal creams, diets, and laser surgery. There is no evidence for their effectiveness, and in fact, some of these treatments may have unintended, negative side effects. Reports have suggested that alternative treatments, such as hypnosis for pain control and acupuncture, have been successful in some women with PVD. However, more research is needed to fully understand the effects of these treatments.

What are pelvic floor muscles (PFMs)?

The PFMs are situated in your pelvic area. They play an important role in bladder and bowel control and sexual function; they are responsible for the closing of the urethral, vaginal, and anal openings. Basically, your pelvic floor muscles can be compared to a bowl supporting your internal organs. In women with PVD, the muscles are attempting to protect them from painful penetration by contracting, which limits further penetration activities and increases the pain. Thus, by relaxing the PFMs, they will increase the diameter of the vaginal opening, and decrease the pain associated with penetrative activities.



How do I perform a PFM contraction? (also known as Kegel exercises)

You can try those contractions/relaxations anywhere, since no one will be able to tell! You can perform the contractions/relaxations while sitting, lying on your back, or lying on your stomach. At the beginning, you may find the contractions difficult to perform, but remember: practice makes perfect! Be patient. It may take weeks before you feel comfortable with performing contractions and relaxations.

1. Sit or lie down comfortably with the muscles of your thighs, buttocks and abdomen relaxed.
2. Tighten the ring of muscle around the urethra and anus as if you are trying to control urine flow, diarrhoea, or wind. Hold the contraction for two seconds. Relax it.
3. Practice this movement several times until you are sure you are exercising the correct muscle. Try not to squeeze your buttocks or thighs.
4. If you are having trouble isolating the PFMs, when you are urinating, try to stop the flow mid-stream, and then restart it. Only do this to learn which muscles are the correct ones to use do not attempt to perform this exercise often, as it may interfere with normal bladder emptying.

Great Websites for more Information

The International Society for the Study of Vulvovaginal Disease www.issvd.org

National Vulvodynia Association www.nva.org

International Society for the Study of Women's Sexual Health www.isswsh.org

Queen's Sexual Health Research

Laboratory's <http://psyc.queensu.ca/faculty/pukall/projects.htm>.

Again, thank you for your participation and do not hesitate to contact us!

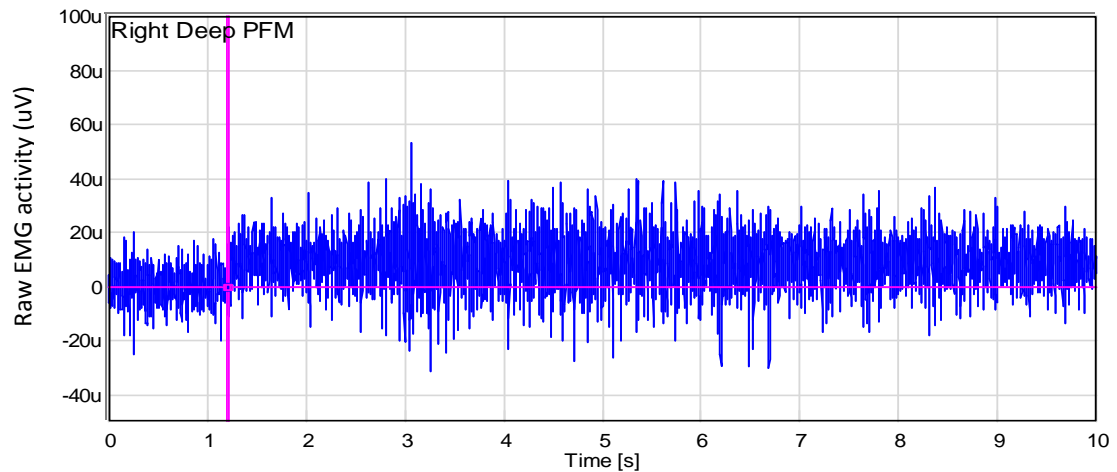
The Research Team

Sexual Health Research Lab @ 613.533.3276 &

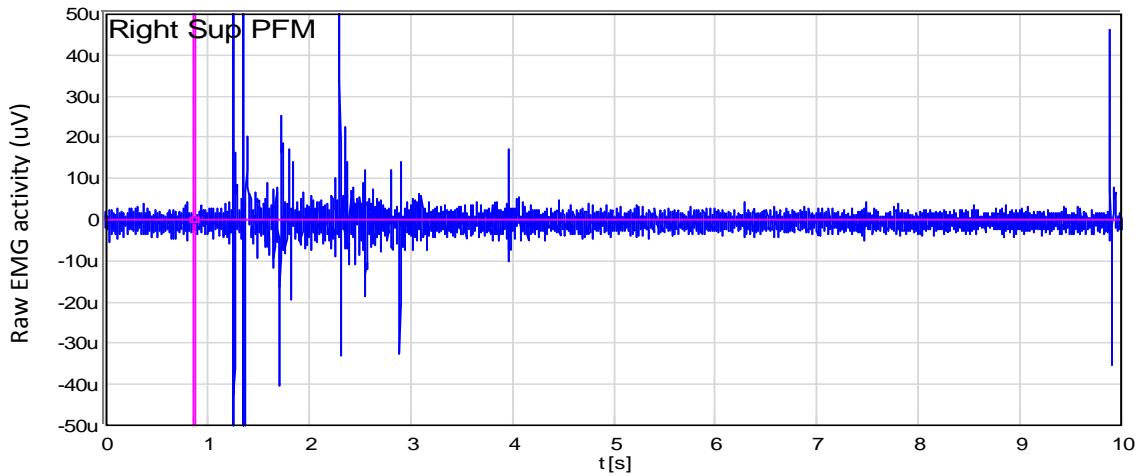
Pelvic Floor Lab @ 613.533.6000 # 79009

Appendix K Excluded EMG Data

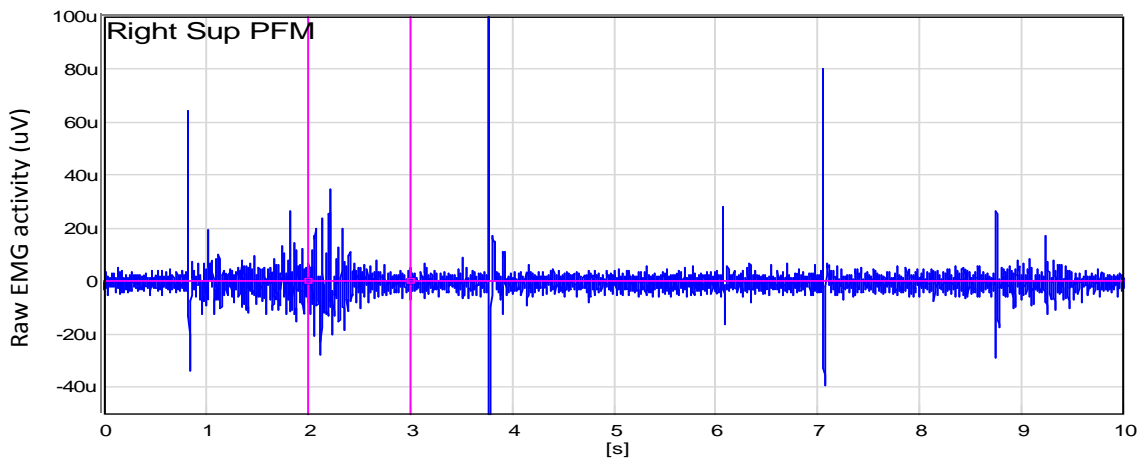
Raw EMG activity expressed in microvolts (uV) over time in seconds (s). The left superficial PFM channel had very high noise in a participant from the PVD group (ID#05, rep 1, set 3). This participant's data were not included in the analysis. The vertical line indicates the time at which the pressure-pain-stimulus (PPS) was applied.



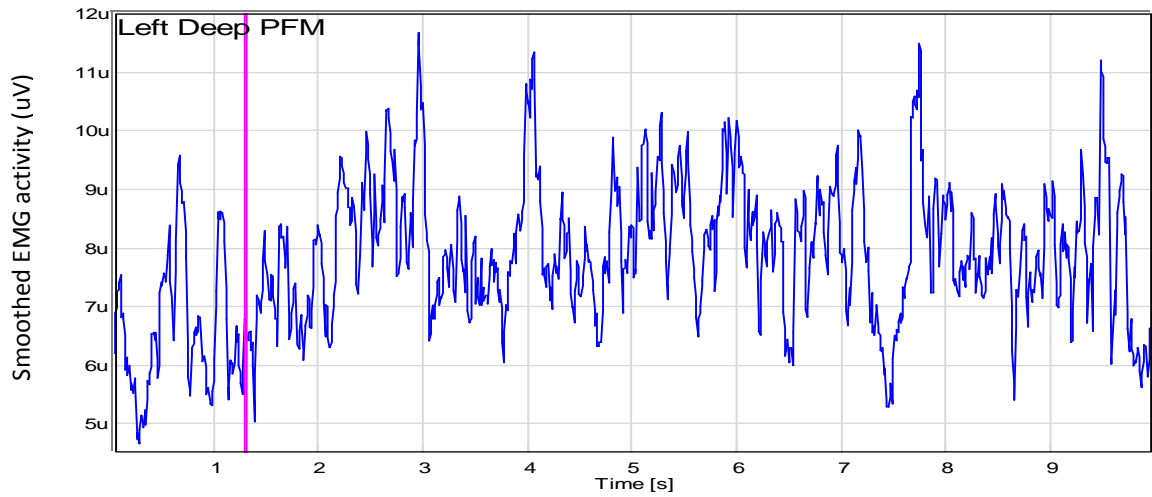
Raw EMG activity expressed in microvolts (uV) over time in seconds (s). The offset seen at 1.3 seconds was caused interference from the footswitch in a participant from the PVD group (ID#4, rep 8, set 10). This occurred in the data of the right deep PFM channel only in the first five participants. These data were excluded from the onset analysis (i.e., Ha5 & 6). The data were included in the Ha 2,3, & a analyses since the offset could easily be removed in order to determine the response amplitudes. The vertical line indicates the time at which the pressure-pain-stimulus (PPS) was applied.



Raw EMG activity expressed in micro volts (uV) over time in seconds (s). The figure shows an example of excessive motion artifact seen on the left superficial PFM channel of a participant in the control group (ID#118, set 7, rep 7). These data were excluded from all analyses. The vertical line indicates the time at which the pressure-pain-stimulus (PPS) was applied.




Raw EMG activity of participant #118 (set 7 - rep 9) over time in seconds (s). This is an example of motion artifact spike in the right superficial channel that prevents onset timing analysis. These data were excluded from the onset analysis (i.e., Ha5 & 6). The vertical line indicates the time at which the pressure-pain-stimulus (PPS) was applied.



Smoothed RMS EMG in microvolts (uV) over time in seconds (s) in the deep PFMs during a PPS application of a participant in the PVD group (ID#4, set 8, rep 6). The EMG response was a very minor rise such that a precise onset time could not be determined using our onset detection method which was observed in 10 out of 33 trials in the PVD group (out of the total 11 excluded trials), and in 12 out of the 33 trials in the pain-free group (out of the 13 excluded data files). The trial was consequently not included in the onset analysis (i.e., Ha5 & 6). The vertical line indicates the time at which the pressure-pain-stimulus (PPS) was applied.

Appendix L Copyrights



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