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A biopsychosocial approach to vulvar vestibulitis syndrome: Diagnostic reliability and treatment outcome

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Table of Contents

Abstract

Vulvar vestibulitis is a highly prevalent and underinvestigated pain syndrome that is considered the most common subtype of dyspareunia, or painful intercourse, in pre-menopausal women. The first chapter of this thesis consists of a critical review of the vulvar vestibulitis literature, covering descriptive, diagnostic, etiologic, and treatment aspects. This is followed by a retrospective study of 38 women, investigating the success of vestibulectomy, a frequently recommended medical treatment for vulvar vestibulitis. Results from structured telephone interviews pertaining to dyspareunia and sexual function show that 63.2% of participants experienced a significant improvement or a complete cure while 36.8% reported moderate to no improvement. The third and fourth chapters are based on a randomized treatment outcome study of women with vulvar vestibulitis. Data from 146 participants taking part in the recruitment phase of the treatment outcome study were used to investigate the reliability of the vulvar vestibulitis diagnosis. Findings demonstrate moderate to substantial inter-rater agreement and test-retest reliability. The fourth paper reports results from the randomized comparison of 78 women meeting study selection criteria and assigned either to group cognitive-behavioral therapy, surface electromyographic biofeedback, or vestibulectomy. They were assessed at pretreatment, posttreatment and 6-month follow-up via gynecological examinations, a structured interview and standard questionnaires pertaining to dyspareunia, sexual function, and psychosocial adjustment. Results from the treatment outcome study demonstrate that 1) participants from the three treatment conditions significantly improve from pretreatment to 6-month follow-up on all pain measures, and 2) vestibulectomy is significantly more successful than biofeedback and group cognitive-behavioral therapy in relieving vulvar vestibulitis. Findings from this set of studies suggest that vulvar vestibulitis can be reliably diagnosed and successfully treated.

Résumé

La vestibulite vulvaire est un syndrome de douleur extrêmement répandu et sous-investigué qui est considéré comme une des sources les plus fréquentes de dyspareunie, ou douleur pendant les relations sexuelles, chez les femmes préménopausées. Le premier chapitre de cette thèse consiste en une revue critique de la documentation sur la vestibulite vulvaire qui couvre les aspects descriptifs, diagnostiques, étiologiques et thérapeutiques. Ceci est suivi d'une étude rétrospective de 38 femmes portant sur le succès de la vestibulectomie, une intervention médicale souvent recommendée pour traiter la vestibulite. Les résultats d'entrevues téléphoniques dirigées ayant trait à la dyspareunie et à la fonction sexuelle démontrent que 63.2% des participantes rapportent une amélioration significative ou une guérison complète alors que 36.8% rapportent une amélioration moyenne, peu d'amélioration, ou aucune amélioration. Les troisièmes et quatrièmes chapitres sont basés sur une étude comparative de traitement de femmes atteintes de vestibulite vulvaire. Dans le troisième chapitre, les données de 146 participantes prenant part au processus de recrutement de l'étude de traitement ont été utilisées afin d'évaluer la fidélité du diagnostic de vestibulite. Les résultats témoignent d'une fidélité inter-juge et d'une fidélité test-retest qualifiées de moyenne à substantielle. Le quatrième chapitre rapporte les résultats de l'étude comparative à répartition aléatoire de 78 femmes rencontrant les critères de sélection et ayant été assignées soit à la thérapie cognitivo-comportementale de groupe, la rétroaction biologique, ou la vestibulectomie. Elles ont été évaluées pré-traitement, post-traitement et à un suivi de six mois par le biais d'examens gynécologiques, d'une entrevue dirigée et de questionnaires ayant trait à la dyspareunie ainsi qu'au fonctionnement sexuel et psychosocial. Les résultats de cette étude démontrent que 1) les participantes des trois traitements s'améliorent de façon significative du pré-traitement au suivi de six mois sur toutes les mesures de douleur et 2) la vestibulectomie est significativement plus efficace que la rétroaction biologique et

que la thérapie cognitivo-comportementale de groupe pour le soulagement de la vestibulite. Les conclusions de cet ensemble d'études suggèrent que la vestibulite vulvaire peut être diagnostiquée de manière fidèle et peut être traitée avec succès.

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Contributions of Authors

This thesis is comprised of four papers. The first one is co-authored by myself and Dr. Irving Binik, Dr. Samir Khalifé, and Dr. Kelly Pagidas. The second one is co-authored by myself and Dr. Céline Bouchard, Dr. Michel Fortier, Dr. Irving Binik, and Dr. Samir Khalifé. The third and fourth papers are co-authored by myself, Dr. Irving Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, and Dr. Howard I. Glazer. The following is a statement regarding the contributions of the six other authors to this work.

The review paper was researched, written, and revised by myself. Drs. Binik, Khalifé and Pagidas served in an editorial capacity. The first study was elaborated, conducted, analyzed and written by myself. Dr. Binik served in an advisory capacity during the formulation of research questions and the development of the protocol, and in an editorial capacity during the writing of the final manuscript. Drs. Bouchard, Fortier and Khalifé conducted the vestibulectomies and provided access to their patients.

In terms of the second study and the two empirical papers which resulted from it, Dr. Binik served in an advisory capacity during the formulation of research questions and the development of protocols, and in an editorial capacity during the writing of the final manuscripts. All data were collected either by myself or by research associates under my supervision, and analyzed by me. I also wrote and revised both manuscripts. Drs. Khalifé and Pagidas added their gynecological expertise to the design of the physical component of the protocol and also performed gynecological examinations of the study participants. Dr. Glazer served as an expert in surface electromyographic biofeedback; he trained and supervised the two psychologists administering this treatment and served in an editorial capacity for the sections of the final manuscript that pertained to biofeedback.

Statement of Original Contributions

The papers included in this thesis contribute to the advancement of knowledge in three domains of research: pain, sexuality, and gynecology. The review of the literature is the first comprehensive and critical review of studies pertaining to vulvar vestibulitis syndrome which clearly positions vulvar vestibulitis as a multifactorial pain condition that should be investigated as such. In addition to constituting a step forward in terms of its methodological rigor, the surgery follow-up study is the first of its kind to assess outcome by an independent investigator, as well as the first to inquire about the impact of this procedure on different dimensions of pain and sexual functioning. The third study represents the first attempt to evaluate the reliability of the vulvar vestibulitis diagnosis and to question the validity of current diagnostic criteria. It is also the first to show that the cotton-swab test is a reliable measure of pain when patient pain ratings are computed systematically. The fourth study is the first randomized treatment outcome study in the area of sexual dysfunction altogether, and the first randomized treatment outcome study of vulvar vestibulitis. As such, it constitutes the most stringent test to date of the efficacy of one of the most frequently recommended gynecological interventions, i. e., vestibulectomy, as well as of biofeedback and cognitive-behavioral therapy. In summary, the research presented in this thesis will impact on how vulvar vestibulitis is conceptualized, investigated and treated in the future, and highlights the necessity of adopting a biopsychosocial approach to study this perplexing pain disorder.

Acknowledgments

This thesis would not have been possible without the help of many dedicated coworkers, the first one being my advisor Dr. Irving Binik, a true pedagogue and mentor. In more ways than I can enumerate here, Dr. Binik has had a major influence on my professional development. He has provided me with the guidance, space, trust and encouragement I needed to pursue and complete a project that was atypical for a thesis but very dear to my heart. Throughout this process, he has been both very supportive and demanding, a combination of attitudes that has helped me go past what I thought were limits to discover a degree of passion for my work that I did not know could exist. For giving me the key to all these doors, a million thanks.

Among the many opportunities Dr. Binik has granted me, an important one was the access to an interdisciplinary research team comprised of highly talented, generous and open-minded health professionals, among which is gynecologist Dr. Samir Khalifé. I thank him for believing in these studies and for giving his expertise and time without counting. He exemplifies the commitment to high quality care and the devotion to patients that one would like to find in every medical doctor. I also thank him, as well as Dr. Kelly Pagidas, for conducting the gynecological examinations and the vestibulectomies. Another pivotal member of our team was Janet Bradley, who coordinated the medical examinations, conducted the structured interviews, and served as the main link between the participants and the researchers. I thank her for lending her organizational skills and her luminous interpersonal qualities to this project. I also thank Dr. Howard I. Glazer, our biofeedback specialist, for training and supervising our therapists in addition to being such a reliable collaborator.

Gynecologists Drs. Céline Bouchard and Michel Fortier from Québec allowed me access to their vestibulectomy patients and by doing so, have enabled me to set the foundations of our treatment outcome study. I thank them for sharing their patients and

hospital resources with me. I also thank Mark Schwartz and Thought Technology as well as Dr. Gary Jarvis, who have generously lent us their equipment and provided crucial advice in our many biofeedback crises.

I thank Dr. Marta Meana, a former graduate student of Dr. Binik's, who has been a pioneering force in his laboratory and has taught and inspired me greatly. She has provided insightful comments on the final manuscript of this thesis. I thank Dr. Karen Berkley and fellow graduate students James Cantor, Ken Mah, and Elke Reissing who made helpful editorial comments on the manuscripts; Caroline Pukall, Dionne Rodrigues and Vivienne Zhao who assisted the gynecologists; Dina Giannopoulos, Louise Labelle, and Terry Peled who were devoted and skilled therapists for the biofeedback and cognitive-behavioral group therapy conditions in our treatment study; Dennis Kalogeropoulos who provided invaluable clinical supervision to the cognitive-behavioral therapists giving the group; and Maria Amore, Geneviève Bédard, Patricia Costantino, and Caroline Pukall, who volunteered countless hours of coding and entering data.

I extend my gratitude to our study participants who have taught me about the complexities of pain and sexuality and who continue to inspire me to pursue research in the area of women's health. I also thank The Fonds pour la Formation de Chercheurs et l'Aide à la Recherche and the Social Sciences and Humanities Research Council of Canada for their financial support.

My immediate and extended family, the Dubreuil family, and my friends have given me instrumental and emotional support throughout the ups and downs of this thesis. I thank them all.

To Étienne, *mon amour*, whose love, support, and humor have been wonderful sources of strength and renewal, I dedicate this work.

Introduction

The major portion of the introduction to this thesis is covered by the first paper, entitled "Vulvar vestibulitis syndrome: A critical review" (Bergeron, Binik, Khalifé, & Pagidas, 1997), which reviews the literature on vulvar vestibulitis to June 1995, and the Literature Review Update, which follows that paper and reports subsequent research.

The rationale for investigating vulvar vestibulitis syndrome lay in the fact that it was the most frequent subtype of dyspareunia in premenopausal women (Friedrich, 1988; Meana, Binik, Khalifé, & Cohen, 1997), which is one of the most prevalent and underrecognized female sexual dysfunctions. There are several reasons why vulvar vestibulitis is best conceptualized within a biopsychosocial perspective and represents an interesting model for studying issues generally included under the rubric of health psychology: 1) vulvar vestibulitis is one of the few pain conditions for which pain can be elicited in a controlled environment, as it is linked to direct sensory stimulation; 2) the pain is located in the female genitalia, which are non-neutral parts of the body; 3) the pain occurs within the context of an intimate activity during which the partner actually causes the pain and witnesses the patient's pain behaviors and emotional reactions, and 4) the etiology of vulvar vestibulitis is unclear and most pathological findings are non significant, thus leaving much room for cognitive interpretations of signs and symptoms.

The research presented in this thesis pertains primarily to the treatment of vulvar vestibulitis. The choice to focus on this aspect of the disorder stemmed from both theoretical and clinical preoccupations. Dyspareunia is one of two female sexual dysfunctions for which there are inadequate data to claim efficacious treatments (Heiman & Meston, 1997); there was thus an urgent need to empirically validate interventions currently used to relieve painful intercourse, and more specifically, vulvar vestibulitis. It also appeared important to determine to what extent psychological approaches could

yield outcomes comparable to that of the standard medical intervention - vestibulectomy. The results of such an investigation had the potential to inform us about possible etiological pathways leading to the development of vulvar vestibulitis and to increase the standards of care for women suffering from this frustrating condition.

The objectives of the first empirical study, "The surgical treatment of vulvar vestibulitis syndrome: A follow-up study" (Bergeron, Bouchard, Fortier, Binik, & Khalifé, 1997) were the following: 1) to determine the suitability of including a vestibulectomy condition in a randomized treatment outcome study we were planning to conduct in the future, 2) to retrospectively evaluate the effectiveness of vestibulectomy in relieving dyspareunia and improving sexual functioning, an 3) to identify factors associated with post-operative outcome. The objectives of the second empirical study, "Vulvar vestibulitis syndrome: Reliability of diagnosis and validity of current diagnostic criteria" (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 1998a) were to assess 1) the reliability of the vulvar vestibulitis diagnosis as defined by Friedrich in 1987, 2) the validity of Friedrich's diagnostic criteria, and 3) the usefulness of these criteria in the diagnostic process. The objectives of the third empirical study, "A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis" (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 1998b) were 1) to prospectively evaluate and compare the differential efficacy of group cognitive-behavioral therapy (GCBT), sEMG biofeedback, and vestibulectomy in relieving dyspareunia as well as improving sexual function and psychosocial adjustment; 2) to contribute to the empirical validation of cognitive, behavioral, and medical interventions in the treatment of dyspareunia.

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Vulvar Vestibulitis Syndrome: A Critical Review

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Abstract:

Objective: Vulvar vestibulitis syndrome (VVS) is thought to be the most frequent cause of dyspareunia in premenopausal women and is one of the major subtypes of vulvodynia. Vulvar vestibulitis is a chronic, persistent clinical syndrome characterized by severe pain on vestibular touch or attempted vaginal entry, exquisite tenderness to a cotton-swab palpation of the vestibular area, and physical findings confined to vestibular erythema. The purpose of this paper is to critically review the descriptive, diagnostic, etiologic, and treatment studies on VVS. Methodological problems are highlighted, and future guidelines for research are proposed.

Data Sources: References were obtained from a MEDLINE search covering the period from January 1984 until June 1995. The indexing term "vulvar vestibulitis" was used, and the search was constrained to English-language articles. References from other relevant sources, such as texts and bibliographies, were also included.

Study Selection: All articles pertaining to VVS were reviewed.

Data Extraction: All data relevant to the descriptive, diagnostic, etiologic, and treatment aspects of VVS were included.

Data Synthesis: Pain symptomatology tends to be underemphasized in the current descriptive studies. The trend in etiological research is to focus on biomedical factors such as candidiasis and human papillomavirus (HPV). Only a few studies adopt a nonreductionnist approach. Surgery is the treatment option with the highest reported success rate. Medical management is underinvestigated, considering its widespread use. Pain management techniques such as biofeedback and behavior therapy show promising results.

Conclusions: A pain syndrome conceptualization is suggested as the most useful approach for solving current empirical and clinical problems.

Key Words: Vulvar vestibulitis syndrome—Dyspareunia—Vulvodynia—Vulvar pain.

The vulvar vestibulitis syndrome (VVS) was probably described over a century ago (1) and is currently thought to be the most frequent cause of coital pain in premenopausal women (2,3). Despite this, it is not mentioned in the most recent edition of the International Association for the Study of Pain (IASP) *Classification of Chronic Pain* (4). A reason for this omission may stem from the fact that gynecologists have only recently begun to recognize the condition as worthy of serious clinical attention.

Vulvar vestibulitis is a chronic, persistent clinical syndrome characterized by severe pain on vestibular touch or attempted vaginal entry, exquisite tenderness to a cotton-swab palpation of the vestibular area,

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and physical findings confined to vestibular erythema (5). It has sparked the interest of a growing number of health care practitioners, including gynecologists, dermatologists, urologists, psychiatrists, and psychologists. The syndrome is considered to be one of the major subtypes of vulvar pain and dyspareunia (2,3,6). Moreover, it is suspected to be increasingly prevalent, with reported rates of ≤15% in general gynecological practice (5,7,8).

The purpose of this paper is to critically review the descriptive, diagnostic, etiologic, and treatment literature on VVS. A pain syndrome conceptualization is suggested as the most useful approach for solving current empirical and clinical problems, and future research guidelines are proposed. References were obtained from a MEDLINE search covering the period from January 1984 until June 1995 and from other relevant sources such as texts and bibliographies.

HISTORY

More than a century ago, Thomas (9) described a condition characterized by "hyperaesthesia of the vulva," with a primary complaint of dyspareunia. Skene (1) provided a similar description in his classic *Treatise on the Diseases of Women* (1889), and in the same year, Kelogg (10) suggested "sensitive points about the mouth of the vagina" as a cause of dyspareunia. Kelly (11) later described tender red spots at the vaginal outlet that often rendered intercourse and pelvic examination impossible. Dickinson (12) found that 73% of his sample of dyspareunic women had a primarily physical cause for their complaint, with a sizeable number suffering from pain involving the hymen, the urethral meatus, and the fourchette. A similar condition was then described by O'Donnell (13), in which he attributed the observed chronic inflammation to incomplete rupture of the hymen. Pelisse and Hewitt (14) were the next to report on 30 cases of "erythematous vulvitis en plaques," a condition in which dyspareunia was the major symptom. They found an acute and chronic inflammation of the subepithelial layers of the posterior vestibule upon histological examination. Subsequently, Davis et al. (15) discussed "vulvitis circumscripta plasma cellularis," which displayed a striking clinica similarity to the condition described by Pelisse and Hewitt (14). At about the same time, Woodruff and Parmley (16) reported on 15 cases of "infection of the minor vestibular glands." These patients presented with complaints of introital discomfort and/or dyspareunia, with symptoms being centered around the vestibule and adjacent hymenal ring. Friedrich (17) also reported in that year of a condition with the same symptoms, which he called "vestibular adenitis." It is impossible to determine whether all of these investigators were referring to the same condition, but the various descriptions share a remarkable similarity. The syndrome has since received other designations, such as "burning vulva syndrome" (18), "focal vulvitis" (19), and "focal vestibulitis vulvae" (20), but most investigators now agree on Friedrich's 1987 proposed terminology of vulvar vestibulitis syndrome (VVS) as the standard nomenclature for this condition (5).

CLINICAL DESCRIPTION

Women suffering from VVS are typically in their 20s and 30s and of Caucasian origin. They complain of a severe, burning pain at the vaginal introitus during penile entry and during other activities such as tampon use, finger insertion, and gynecological examinations (3,5,7,8,16,21–27). Postcoital burning is also often reported and can persist for several hours or even days (24,27). The lack of physical findings may result in a woman being told by her gynecologist that nothing is wrong and that the problem is psychological (16,21,28,29). Until a diagnosis of VVS is considered, the most common treatments are a variety of vaginal creams, which are usually unsuccessful (see Treatment).

Typically, vestibular pain can develop either gradually or suddenly, following a period of pain-free intercourse, or during the first intercourse attempt. In the latter case, the syndrome is classified as primary, and in the former, as secondary (3,7,22). These authors report an approximately even split between primary and secondary onset.

There is almost universal agreement that VVS impacts greatly on sexual functioning, affecting both the quality and the frequency of sexual activities. Despite this, empirical data are scarce. In the only controlled empirical study, Meana et al. (3) found that compared with matched controls, women with VVS had a significantly lower frequency of intercourse, lower levels of desire and arousal, and less orgasmic success with intercourse and manual stimulation by the partner. Along the same lines, Schover et al. (27) found that 51% of the women in their sample had low sexual desire, 57% had poor lubrication, 57% had situational anorgasmia, and 60% suffered from vaginismus.

Standard pelvic examinations typically reveal no disease or abnormality. The findings obtained through other gynecological exams are usually limited to known organic problems and cannot be directly linked to the experience of pain. Histopathological studies to date have demonstrated only a chronic, nonspecific inflammation of the vestibular area, affecting mostly the superficial stroma and sometimes the epithelium (5,8,19,24,26,30–32). The vestibular glands, which are not found in all women and whose function remains unknown, are not usually affected by the inflammation. In fact, they can even be absent from the affected vestibular areas (5,19,32).

DIAGNOSIS

The diagnosis of VVS is entirely based on clinical observations. Friedrich (5) established the following diagnostic criteria: (a) severe pain on vestibular touch or attempted vaginal entry, (b) tenderness to pressure localized within the vulvar vestibule, and (c) physical findings confined to vestibular erythema. Despite the absence of studies regarding their diagnostic validity and reliability, many researchers implicitly or explicitly work with these useful criteria. Friedrich's first criterion refers to introital dyspareunia and does not in itself serve to differentiate VVS from other conditions that are a source of superficial coital pain. The method used to investigate the second criterion is the cotton-swab test, a procedure in which a cotton-tipped applicator is used to localize pain in the posterior part of the vestibule. Finally, Friedrich's third criterion, the presence of vestibular erythema, may be difficult, considering that this finding is not consistently reported by gynecologists and that distinguishing varying levels of redness may not be a reliable clinical procedure except at the extremes. Moreover, erythema is a common symptom of many vulvar diseases.

Aside from Friedrich's criteria, other relevant information is usually taken into account to formulate the diagnosis of VVS. In a recent report, the International Society for the Study of Vulvar Disease states that VVS is a chronic and persistent condition that "does not include symptoms associated with acute inflammatory conditions or with immediate postoperative changes; those symptoms resolve with appropriate therapy or after a reasonable postoperative period" (33). An arbitrary but reasonable cutoff point of a 6-month-symptom-duration period has been suggested by various investigators (2,19,28).

VVS must be differentiated from a broad range of vulvar and coital pain conditions that may be confused with it. The syndrome is currently considered to be a subset of vulvodynia, a general condition characterized by chronic, unexplained vulvar pain with associated complaints of burning, stinging, irritation or rawness, and minimal physical findings (29,34). Apart from VVS, vulvar dermatoses, cyclic vulvovaginitis, vestibular papillomatosis, and dysesthetic vulvodynia are usually included in this category (6,35).

The syndrome is also gaining increased attention as a significant contributor to coital pain. Indeed, it has been loosely classified as an organic cause of dyspareunia in the psychology literature (e.g., 36). As such, it needs to be distinguished from several other gynecological problems that have been found to cause pain upon intercourse. Meana et al. (3) have classified these problems as follows: (a) vulvar/vaginal atrophy, which consists of a thinning of the vulvar and vaginal mucosa generally attributed to an estrogen deficiency in postmenopausal women; (b) physical findings other than VVS and vaginal atrophy, including problems such as pelvic conditions and prolapsed uterus, among others; and (c) coital pain without any indication of a physical cause. Finally, some of the syndromes classified in the vulvodynia category, such as cyclic vulvovaginitis, can also be the source of painful intercourse.

There is still some confusion about how to distinguish the various vulvar and coital pain conditions. Many overlap and co-occur, such as cyclic vulvovaginitis and vestibular papillomatosis, both of which have also been associated with the onset of vulvar vestibulitis (3,28,37–45). Although some authors have attempted to outline general principles to distinguish VVS from other types of vulvar or coital pain (35,46), there is a paucity of empirical investigations of the pain symptomatology in the VVS literature.

ETIOLOGY

A wide range of factors has been proposed to explain the etiology of VVS. Most of them are derived from clinical case reports rather than controlled studies. The result is a wide variety of interesting but unsubstantiated hypotheses.

Candidiasis

A history of recurrent candidiasis infections is one of the most consistently reported findings associated with the onset of VVS (5,19,27,28,42,47–49). Two studies have compared the gynecological histories

of vulvar vestibulitis patients with those of control subjects (3,40). Both investigations found that women with VVS had suffered from significantly more *Candida* infections than normal controls, with ≤80% of the patients having a positive past history as opposed to 21% for controls. However, this association is based on patient self-report of past infections, and attempts to document a current infection at the time of the study have been disappointing (24). Indeed, both Meana et al. (3) and Bazin et al. (22) failed to find a high prevalence of culture-documented *Candida* infections among their samples. It is difficult to determine whether women are reporting on past gynecological diagnoses or self-diagnoses that were inaccurate, or whether they previously suffered from authentic *Candida* infections.

Two additional studies explored the link between VVS and candidiasis. Marinoff and Turner (42) were unsuccessful in their attempt to demonstrate a hypersensitivity to *Candida* in women with VVS. Pyka et al. (32), in their histopathological study, were not able to detect any infiltrate indicative of a delayed-type hypersensitivity.

Human papillomavirus

Human papillomavirus (HPV) infections have long been considered to play a major etiological role in the development of VVS (8,44,45). However, the initial studies investigating this association lacked control groups. In addition, histologic diagnosis of HPV infection in the vulva is much less reliable than that in the cervix. The virus is thus presumed to be overdiagnosed (6,27,46). Even when the polymerase chain reaction (PCR) technique is utilized, results are contradictory. Findings from two case-control studies conducted with this technique show that HPV was present in only 5.3–9.7% of the women with VVS, frequencies no different than those of controls (22,50). In a similar study, Bergeron et al. (51) failed to find evidence of HPV in any of their subjects with VVS. In contrast, Umpierre et al. (45) detected HPV using PCR in 85% of their cases, although sample size was small. Another controlled study demonstrated that patients with VVS reported significantly more past condylomata infections, which are caused by HPV, than normal controls (40). No biopsy specimens were analyzed. Using in-situ hybridization analysis, Prayson et al. (31) were unable to substantiate the etiological role of HPV in VVS. Finally, Goetsch (7) found that only a minority of subjects in her study had a known history of HPV infection, although there was no comparison group. More controlled studies are needed to elucidate the current confusion surrounding the association between HPV and VVS.

Iatrogenic factors

Many authors have suggested that antifungal and other prescribed vaginal creams may in fact play a role in the development of VVS (7,27,28,35). The recent transformation of these agents from prescription status to "over-the-counter" status may cause further damage. Fluorouracil, used to treat human papillomavirus infections and condylomata acuminata, is suspected of aggravating the syndrome (46). Systemic antibiotics and topical steroids, both prescribed in suspected cases of vaginitis, may also be harmful. The potential role of iatrogenic effects has not been empirically demonstrated but does constitute a seemingly frequent clinical observation worthy of further investigation.

Immune function and allergies

Ashman and Ott (37) suggested that autoimmunity might be a factor in recurrent vaginal candidosis and VVS. On the basis of data from animal studies, they proposed that in some susceptible individuals, antigens of *Candida albicans* are cross-reactive with certain vulvovaginal tissue antigens, thereby aborting an effective immune response against the organism. They further postulated that after repeated infections, the immune system of these susceptible individuals becomes hyperreactive against the cross-reactive antigens, thus weakening the immune response and creating local inflammatory responses initiated by these self-reactive cells. The authors hypothesized that these responses could be triggered by hormonal changes or other stresses. Pyka et al. (32) were unable to confirm or deny an immune complex basis for VVS through histopathological observation, nor did they find evidence of an allergic reaction.

Friedrich (5) reported that 48% of the women in his sample were allergic to one or more substances. These data, however, were based on self-reports rather than allergy testing, and the study lacked a comparison group. In a pair-matched case-control study based on self-reporting, Mann et al. (40) found that histories of multiple allergies were significantly more prevalent in the patient group than in the control group (59% as opposed to 31%). No specific type of allergy was reported with greater frequency. Through the use of patch tests, Marinoff and Turner (42) were unable to confirm the presence of an allergic or irritant reaction to topical therapies prescribed for vaginal candidiasis in their sample of 13 women.

Finally, an autoimmune response was also proposed as the mechanism underlying the observed association between vulvar vestibulitis and interstitial cystitis, although no supporting data were presented (25).

Hormonal factors

Bazin et al. (22) found that women who had first used oral contraceptives before the age of 17 had an 11-fold increase in relative risk of developing the syndrome. Early menarche was also associated with an increased risk. The authors hypothesize that the role of the mucus secreted by the vestibular glands may be to protect the fragile vulvar epithelium of the vestibule against vaginal secretions. Hormones contained in oral contraceptives could modify the quality and quantity of the mucus, leading to a diminished protection of the vestibule, which would then become chronically irritated through the low-pH vaginal discharge of the reproductive years.

Other related observations pointing toward a hormonal etiology include a reported increase in pain intensity immediately preceding menses (19,27,52). Similarly, others have noticed that symptoms vary depending on the period in the menstrual cycle (5). Moreover, estrogen therapy and high-dose estrogen oral contraceptives have both been associated with increased asymptomatic vaginal colonization of *Candida* and candidal vaginitis, the factor most commonly linked to VVS (53). Interestingly, Goetsch (7) noted that for 21% of the women in her study, VVS had started post partum, even when the infants had been delivered by cesarean section. Furthermore, the post-partum time was often recalled as the time of worst pain by those already suffering from VVS.

Urethral conditions and sympathetically maintained pain

A hypothesis that has recently received increasing attention is the association between urethral conditions, vulvar vestibulitis, and sympathetically maintained pain. A link between VVS and interstitial cystitis was suggested by McCormack (25), who reported that the two conditions occurred together in a high proportion of women in his sample. The syndromes were again associated in a recent case report study of three women suffering from both conditions (54). Interestingly, the tissues involved in the syndromes (bladder, urethra, and vestibule) all derive from the embryonic urogenital sinus. Both conditions remain misunderstood and are important causes of genitourinary pain in young women, with physical findings limited to nonspecific inflammation.

A related finding is that of Peckham et al. (19), who reported that six of the nine women who participated in their in-depth clinical investigation had a history of prior urinary tract infection. Schover et al. (27) also found that 31% of their patients had a history of repeated urinary tract infections. Both studies relied on patient self-reporting.

Another group of researchers found that women with VVS displayed significantly greater urethral pressure variability than did normal controls and other chronic pain subjects, after age, race, and parity were controlled for (23), even though there was not a significant difference in the proportion of urinary tract complaints between groups. The authors attributed this variability to a variation in muscle tone of the urethra. They believe that their data may link VVS to sympathetically-maintained pain. This type of pain is characterized by continuous burning and is exacerbated by movement, stimulation, or stress. Vasomotor instability and muscle spasm may be present as well (4). Other researchers have also proposed that vulvar pain syndromes and interstitial cystitis may constitute sympathetically maintained pain, sometimes referred to as "reflex sympathetic dystrophy" (6,35,55,56). The therapeutic success of biofeedback (for pelvic floor muscles) in alleviating vulvar pain, as suggested by Glazer et al. (55) (see Treatment), lends support to the hypothesis that an autonomic pain mechanism may play a role in the etiology and maintenance of VVS.

Vaginismus

Some clinicians have observed that women suffering from VVS present with concomitant vaginismus (27,35,47). It is not clear from these reports whether the vaginismus is thought to precede or result from vulvar vestibulitis, nor is the method for diagnosing vaginismus and distinguishing it from VVS ever specified. However, this mechanism could explain some of the reported success in treating VVS through vaginal dilatation (47,57).

Genetic predisposition

Goetsch (7) and Bergeron et al. (58) reported that between one-quarter and one-third of the women in their samples knew of a female relative with dyspareunia or "intolerance of tampons." In Goetsch's study, the association was strongest with close family members of women who had primary VVS: eight out of ten knew of a female relative suffering from coital pain. None of these studies had matched control groups.

Some support for a genetic predisposition can also be drawn from the observation that women suffering from VVS are primarily of Caucasian origin (5,7,19,24,27,28,55). Some authors have suggested that this may reflect an anatomic variation in the sensitivity of the vestibular tissue (46). Other sociocultural and socioeconomic factors can also explain this clinical observation.

Calcium oxylate

One group of researchers has suggested that excess oxalate in the urine irritates the vulvar epithelium, causing severe burning (52). In their case study of a patient who suffered from symptoms of vulvar vestibulitis as well as from generalized vulvar pain, they noticed that the degree of fluctuation in the urinary constituents (pH, oxalate, etc.) was greater in the patient than in related and unrelated controls. This intriguing finding has not been replicated since, and to our knowledge, no other studies pertaining to calcium oxylate or diet have been published to date.

Psychological factors

There is little mention in the literature of psychological factors as etiological agents. Psychological issues are discussed mainly in the context of the emotional support provided to patients in the treatment of the syndrome. Two empirical studies have attempted to investigate the possible role of psychological variables in VVS. Schover et al. (27) found that the 27 women who completed their psychological evaluation scored within norms on measures of couple adjustment and general psychological adjustment. Further inquiry through structured interviews revealed that the onset of pain was often linked to a stressful period in the women's life, such as difficulty in a relationship. The authors also reported that the interview data, contrary to questionnaire data, suggested that relationship conflict, somatization disorder, and depressive symptoms appeared to be particularly common among these women. They attribute this discrepancy to the patients' reluctance to relate their vulvar pain to psychologic stress. This finding requires confirmation with a larger sample, a matched control group, and more standardized measurements.

Meana et al. (3) found no differences between 54 VVS patients and normal, matched controls on measures of general psychological adjustment (Brief Symptom Inventory) and relationship adjustment (Locke-Wallace Marital Adjustment Scale). With regard to sexuality, they found that women suffering from VVS were significantly more erotophobic than controls, having more conservative attitudes towards sexuality.

TREATMENT

On the basis of the existing studies, the literature on VVS treatment can be divided into three categories: surgical interventions, medical management, and cognitive-behavioral/pain management therapy.

Surgery

Surgical interventions consist of vestibulectomy and laser therapy. Vestibulectomy has been the most frequently investigated treatment for VVS and the one most consistently reported as achieving the best therapeutic outcome. The 20 studies are summarized in Table 1. The surgery, first proposed by Woodruff and Parmley (16) and often referred to as modified perineoplasty, consists of an excision of the hymen and of all the sensitive areas of the vestibule, most frequently located in the posterior fourchette, to a depth of ~2 mm. The vaginal mucosa is then mobilized and brought downward to cover the excised area (5,28). This procedure is typically carried out as day surgery with the patient under general anesthesia. Healing of the area lasts 4–8 weeks and includes sitz baths and ice packs to relieve immediate discomfort. Women are typically instructed to gradually resume intercourse after ~8 weeks (40,59). Vestibulectomy is usually recommended following the failure of medical management, as is laser therapy.

Laser treatment is a controversial modality and is suspected to have potentially aggravating effects (6,46). To our knowledge, only three treatment outcome studies have been conducted using this type of surgery (see Table 1). The CO_2 laser technology was used in the 1980s for ablation of the vestibular area to a depth of 1.5 mm to 1 cm. More recently, the flashlamp-excited dye laser technique was the subject of a large study undertaken by Reid et al. (56). It is thought to have less negative consequences than the CO_2 laser technique.

Success, although never clearly defined, is usually reported in terms of complete cure or significant improvement. It is typically measured through a one-time self-report rating of pain during intercourse. Success rates range from 43 to 100% for excisional surgery, with the majority of estimates surpassing the 60% mark; reported success for laser surgery ranges from 53 to 66% (see Table 1). Unfortunately, these conclusions are weakened by multiple methodological flaws. Control groups are missing in most of the

TABLE 1. *Surgery outcome studies for vulvar vestibulitis syndrome*

Reference	Sample characteristics (N, age, SES, misc.)	Treatment	Design	Definition of VVS	Other selection criteria	Pain measurement	Follow-up	Outcome	Comments*
Friedrich (5)	N 38; age 18–75*; SES ?; misc. ?	Wendroff's perineoplasty (+ excision of hymen and sensitive vestibular areas)	Retrospective case series	Friedrich's criteria	?	Self-reported pain (4 pt. scale) before and after surgery, self-reported symptom change (5 pt. scale)	≤ 3 yr	29/38 complete relief or much improved, 15/38 some relief, no relief or worse	1,2,3,4,6
Reid et al. (8)	N 22; age 18–80;* SES ?; misc. ? had vestibular acetowhitening; ? had cervical HPV; ? had treatment for condylomas	Wendroff's perineoplasty (hymenal resection)	Quasiexperimental clinical study	Friedrich's criteria	Vulvar burning	?	?	13/22 complete relief or much improved; 9/22 no relief	2,3,5,6
Wendroff and Parmley (16)	N 14; age 22–39; SES ?; misc. ?	Wendroff's perineoplasty (+ excision of hymen & adjacent .5 cm of tissue)	Retrospective case series	Dyspareunia; vestibular tenderness	?	?	6 mo–3 yr	11/14 much improved	1,2,3,4,6
Peckham et al. (19)	N 8; age ?; SES ?; misc. ?	Wendroff's perineoplasty	Quasiexperimental clinical study	Dyspareunia; nonspecific vestibular inflammation	?	?	At least 5 months	7/8 complete relief	2,3,4,6
Michlewitz et al. (26)	N 30; age 19–44*; SES ?; misc. all had pain at Bartholin duct opening	CO_2 laser (ablation to a depth of 5 mm–1 cm); 21 had laser to Bartholin duct only, 9 to duct and adjacent	Quasiexperimental clinical study	Dyspareunia with severe restriction of sexual function; vestibular tenderness	?	Self-reported sexual function, before & after surgery (10 pt. scale)	?	15/30 complete relief or much improved; 3/30 improvement; 14/30 no relief	2,3,4,6
Michlewitz et al. (26)	N 16; age 19–44;* SES ?; misc. 8 had laser treatment and all had pain at Bartholin duct opening	Perineoplasty (excision of elliptical specimen; area between hymen and perineal body ridge)	Quasiexperimental clinical study	Dyspareunia with severe restriction of sexual function; vestibular tenderness	?	Self-reported sexual function, before & after surgery (10 pt. scale)	?	16/16 complete relief or much improved	2,3,4,6
Schover et al. (27)	N 38; age 19–45; SES 74% white collar, 27% blue collar; misc. 51% had deep dyspareunia;	Involved areas were excised (hymen left intact); 16 had a psychologic evaluation & partup. sex therapy	Retrospective case series	Friedrich's criteria	?	Structured phone interview (pain & sex); outcome, 5 pt. scale	1–24 mo	18/38 much improved; 14/38 improvement; & 38 no relief	1,2,3,5,6
Marinoff and Turner (28)	N 73; age ?; SES ?; misc. ?	Wendroff's perineoplasty (+ inclusion of periurethral areas)	Retrospective case series	Friedrich's criteria	Dyspareunia >6 mo, sometimes preventing intercourse; no apparent cause	?	?	60/73 complete relief; 11/73 improvement, 2/73 no relief	1,2,3,4,6

TABLE 1—(*Continued*)

Reference	Sample characteristics (N, age, SES, misc.)	Treatment	Design	Definition of VVS	Other selection criteria	Pain measurement	Follow-up	Outcome	Comments*
Barbero et al. (30)	N 21; age 18–39; SES ?; misc. all had membranous hypertrophy of the posterior fourchette; 8 had chronic vulvar pain; 10 had antifungal treatment	Excision of membranous hypertrophy of fourchette & of posterior portion of vestibule	Retrospective case series	Friedrich's criteria	?	?	1 mo	19/21 complete relief, 2/19 improvement	1,2,3,5,6
Mann et al. (40)	N 56; age ?; SES ?; ? had pruritus, vaginal discharge	Perineoplasty	Retrospective case series	Friedrich's criteria	?	Mail questionnaire (pain & intercourse)	6 mo–4.5 yr	37/56 complete relief or much improved; 12/56 improvement; 7/56 no relief	2,3,5,6
Marinoff et al. (41)	N 19; age 21–54;[b] SES ?; misc. all had interferon; ? had HPV	Modified vestibulectomy (perineoplasty)	Quasiexperimental clinical study	Friedrich's criteria	Dyspareunia >6 mo, sometimes preventing intercourse	Self-reported pain (intercourse & gynecological exam); degree of erythema	?	14/19 much improved; 2/19 improvement; 1/19 no relief	2,3,5
Abramov et al. (47)	N 7; age 22–40;[b] SES ?; misc. 3 had past treatment for vaginismus	Distal excision of hymenal ring for ~1 cm; excision of vestibular glands + orifices of Bartholin ducts	Quasiexperimental clinical study	Friedrich's criteria	No serious marital, sexual, or mental health problems; no deep dyspareunia; no vaginal dryness; eradication of local infections if any	?	3 mo 6 mo 1 yr	5/7 complete relief at 3 mo; 2/7 complete relief at 6 mo (after 3 mp of sex therapy)	2,3
Reid et al. (36)	N 104; age 16–74;[b] SES 90% had completed high school & 30% had a baccalaureate degree; [b] misc. 43 also had deep dyspareunia; ? had concurrent candidiasis	Pinhlump-excited dye laser	Quasiexperimental clinical study	Friedrich's criteria	Refractory to medical therapy	4 semisubjective pain scales (dyspareunia & interval pain)	median 2.6 yr	Surface dyspareunia: 41/61 complete relief, 16/61 improvement, 4/61 no relief Surface + deep dyspareunia: 9/43 complete relief, 9/43 improvement, 32/43 no relief	2,3
Weijmar Schultz et al. (57)	N 13; age 18–30;[b] SES ?; misc. ?	Modified Woodruff's perineoplasty (excision of the hymen & adjacent vulvar tissues) & average of 13.1 behavior therapy sessions	Partly randomized clinical trial	Friedrich's criteria	Symptoms >6 mo; chronic nonspecific inflammation; no active infection; not pregnant; no surgery <6 months; no treatment <2 months; ages >18; Dutch;	Phone interview (outcome, 5 pt. scale)	2–36 mo	7/13 complete relief, 4/13 improvement, 2/13 no relief but less of a problem	2,3,6

Bergeron et al. (58)	N 38, age 19–52; SES average of 1st year college education, misc. all had past medical treatments	Vestibulectomy (excision of involved vestibule & hymen, Woodruff 1983)	Retrospective case series	Friedrich's criteria	Moderate to severe interference with intercourse; no active infection	Structured phone interview (pain, sex, other treatments)	1.1–9 yr	In 36 complete relief, 1/38 much improved, 7/38 little or no relief	1,2,3
Woodruff and Friedrich (59)	N 44, age ?; SES ?, misc. ?	Woodruff's perineoplasty (+ excision of hymen & adjacent glands)	Retrospective case series	Dyspareunia; tenderness at outlet	?	?	?	36/44 complete relief, 6/44 improvement, 2/44 no relief	1,2,3,4,6
Woodruff et al. (78)	N 18, age 21–70, SES ?; misc. ? had pruritus, itching, condylomas, & vaginal surgery	Woodruff's perineoplasty	Retrospective case series	Dyspareunia	?	?	6 mo–5 yr	18/18 complete relief	1,2,3,5,6
Davis (79)	N 30, age 19–44; SES ?; misc. 12 had laser in past for condylomas, 3 had cryosurgery & all had past medical treatments	CO_2 laser (ablation to a depth of 1.5–2.5 mm of vestibule below urethra)	Retrospective case series	Friedrich's criteria	No treatable etiological agent	?	1 yr	20/30 complete relief or much improved; 10/30 no relief	1,2,3,4,6
de Jong et al. (80)	N 14; age ?; SES ?; misc. ?	Woodruff's perineoplasty	Retrospective case series	Friedrich's criteria	No clear organic cause; symptoms >6 mo	Questionnaire & semistructured interview (pain & sex)	3–7 yr	3/14 complete relief; 3/14 improvement, 8/14 no relief	1,2,3,4,6

N, sample size; age, age range; SES, socioeconomic status; misc., miscellaneous information.

[a] 1, no control/comparison group; 2, no random assignment; 3, nonblind treatment evaluation; 4, little information on sample selection procedures/sample characteristics not well defined; 5, heterogeneous sample; 6, no definition of therapeutic success.

[b] For whole sample as opposed to only for this surgery group.

studies, pain measurement is rudimentary or not specified at all, length of follow-up varies considerably within and between studies, and therapeutic success is seldom clearly defined. Furthermore, uniformly standardized protocols are rare; selection criteria are either minimal, unclear and/or unsystematic; and evaluation of treatment is always nonblind, rendering it highly subjective (for more details, see Table 1). The variation in surgical techniques creates another problem. Additionally, the possible occurence of other treatments during the period between the surgery and the follow-up inquiry are never mentioned, making it impossible to attribute the improvement in pain solely to the surgical procedure.

Some authors state that conjoint sexual counseling, consisting primarily of dilatation exercises, enhances surgery outcomes (27,47,57). For example, Schover et al. (27) found that the women who had at least one session of postoperative sex therapy had significantly better outcomes than those who refused this session. The explanation they provide is that this additional sexual counseling may remove some of the muscle tension (vaginismus) and low sexual arousal (poor lubrication) that have resulted from longstanding dyspareunia and that contribute to vulvar irritation.

Medical management

Medical management usually involves the application of a variety of topical ointments such as anesthetics, antifungals, and antibiotics; the prescription of systemic medications; and other treatments such as interferon. Reports of medical management efficacy range from clinical accounts to empirical studies. We found a total of 11 empirical studies, all of which are included in Table 2. References cited in the text but not included in the table are articles on nonempirical accounts.

Topical anesthetics such as lidocaine jelly have been thought to relieve discomfort temporarily and make intercourse possible in some milder cases of vulvar pain (60,61). Lubricants such as vegetable shortening are also recommended for the same reasons (62–64). Antifungal, antibiotic, antiviral, and corticosteroid creams are generally considered to be ineffective in the treatment of the syndrome, although to our knowledge no controlled clinical trials have been conducted (2,16,19,26,40,65).

Friedrich (2) conducted small, uncontrolled pilot studies comparing five different medications: isotretinoin, dapsone, and acyclovir taken orally, and progesterone and capsaicin applied topically (see Table 2). Length of follow-up varied across the studies. The results demonstrated that half of the women who were prescribed acyclovir reported a decrease in severity and duration of their pain. The other drug found to be of help was capsaicin: over half of the women in the group using it significantly reduced or eliminated their pain and tenderness. Capsaicin has been used in cases of reflex sympathetic dystrophy and other chronic pain syndromes (66). Considering that the initial applications of topical capsaicin are exceedingly painful, future studies with other substance P antagonists that are less potent inflammatory agents may be useful.

Intralesional alpha interferon injections have not received approval from the United States Food and Drug Administration as a treatment for VVS but are approved for the treatment of condylomata. They are thus usually reserved for patients presenting with concomitant HPV infections. If colposcopic or biopsy findings are devoid of HPV changes, alpha interferon injections should not be utilized for the treatment of VVS. Interferon, which has immunomodulatory, antiviral, and antiproliferative properties, is generally injected into the affected area of the vestibule several times a week for ~4 weeks (67). Reported success rates range from 38 to 88%, with the majority of results situated around the 50% mark (see Table 2). Some unpleasant side effects are reported, such as low-grade fever and flu-like symptoms (63). Although this treatment option is time-consuming and expensive, the studies to date yield promising results.

Calcium citrate tablets prescribed to modify oxalate crystalluria were attributed the complete relief of vulvar pain in one reported case (52). Amitriptyline has been mentioned in the literature as a possible treatment for VVS; although one author reports that it appears not to be very effective for this subset of vulvodynia patients (68), the use of tricyclic antidepressants in low doses may warrant further study, as this type of medication is widely used in pain management.

Pain management

Pain management for VVS has consisted of modalities such as behavior and sex therapy, biofeedback, cold application, and acupuncture. Abramov et al. (47) noted that three of the seven women in their sample who were offered sexual counseling and treatment with vaginal dilators because of suspected vaginismus were able to resume intercourse. The authors did not describe the treatment program. Weijmar Schultz et al. (57) found that a combination of surgery and behavior therapy was not significantly more ef-

TABLE 2. *Nonsurgical treatment outcome studies for vulvar vestibulitis syndrome*

Reference	Sample (N, age, SES, misc.)	Treatment	Design	Definition of VVS	Other selection criteria	Pain measurement	Follow-up	Outcome	Comments*
Friedrich (2)	N 43; age ?; SES ?; misc. ?	Oral and topical drugs (isotretinoin, dapsone, acyclovir, progesterone cream, capsaicin cream)	Quasiexperimental clinical study	Friedrich's criteria	Symptoms >6 mo	Diagram for degrees of tenderness at vestibular sites (5 pt. scale), self-reported pain severity and duration	0–11 mo	Isotretinoin & progesterone not effective; Dapsone: 3/14 improvement, Acyclovir 7/13 improvement, Capsaicin .4/6 improvement	2,3,6
Bornstein et al. (38)	N 7; age 18–25; SES ?; misc. ?	Intramuscular interferon injections	Quasiexperimental clinical study	Friedrich's criteria	HPV; no treatments in 6 mo; sensitivity on 2 sides of vestibule	?	6–18 mo	4/7 complete relief, 1/7 improvement; 1/7 no relief	2,3,6
Kent and Wisniewski (39)	N 8; age 28–33; SES ?; misc. ?	Intralesional interferon injections	Retrospective case series	Dyspareunia; vestibular tenderness	HPV; vestibular aceto-whitening	?	3–9 mo	2/8 complete relief after 1 series of injections, 3/8 complete relief after 2 series of injections, 3/8: no relief	1,2,3,4,6
Mann et al. (40)	N 13; age ?; SES ?; misc. ? had pruritus, vaginal discharge, and/or HPV	Intralesional interferon injections	Retrospective case series	Friedrich's criteria	?	Mail questionnaire (pain & intercourse)	6 mo–4.5 yr	5/13 much improved; 7/13 somewhat improved; 1/13 no relief	2,3,5,6
Marinoff et al. (41)	N 55; age 21–54;[a] SES ?; misc. 46 had HPV	Intralesional interferon injections	Quasiexperimental clinical study	Friedrich's criteria	Dyspareunia >6 mo, sometimes preventing intercourse	Self-reported pain (intercourse & gynecological exam); degree of erythema	1 mo–3.2 yr	10/55 much improved, 17/55 improvement; 28/55 no relief	2,3,5

TABLE 2—(*Continued*)

Reference	Sample (N, age, SES, misc.)	Treatment	Design	Definition of VVS	Other selection criteria	Pain measurement	Follow-up	Outcome	Comments*
Umpierre et al. (45)	N 13; age 29–53; SES ?; misc. 11 had HPV; 1 or + had vulvar burning, irritation or itching, dyspareunia, vulvar pain	Intradermal interferon injections	Retrospective case series	Vestibular tenderness; acetowhite changes in vestibule	?	?	?	5/11 (HPV) improvement; 6/11 (HPV) no relief; 2/11 (no HPV) no relief	1,2,3,4,5,6
Abramov et al. (47)	N 7; age 22–40;[b] SES ?; misc. ?	Treatment with vaginal dilators	Quasiexperimental clinical study	Friedrich's criteria	Vaginismus; no serious mental, sexual, or mental health problems; no deep dyspareunia; no vaginal dryness; eradication of local infections if any	?	?	3/7 improved vaginismus but not VVS; 3/7 complete relief; 1/7 no relief	2,3
Solomons et al. (52)	N 1; age 32; SES ?; misc. HPV & other types of vulvar pain	Calcium citrate; low-oxalate diet; increased fluid intake; vitamin B_6	Single-case study	Pain at vaginal entry; vestibular tenderness	?	Pain diary (frequency)	1 yr starting at treatment	At 3 months, improvement; At 1 year: complete relief	1,2,3,6
Glaser et al. (55)	N 33; age 21–45; SES ?; misc. 27 took amitriptyline; ? had chronic vulvar pain	Biofeedback	Retrospective case series	Dyspareunia; vestibular tenderness	Sensitive pelvic floor muscles	Self-reported pain (10 pt. scale); intercourse frequency 30 days prior to last assessment	6 mo	83% average pain decrease; 17/33 complete relief	1,2,3,4,5,6
Weijmar Schultz et al. (57)	N 35; age 19–39;[b] SES ?; misc. ?	Behavioral treatment (sex therapy)	Partly randomized clinical trial	Friedrich's criteria	Symptoms >6 mo; chronic nonspecific inflammation; no active infection; not pregnant; no surgery <6 mo; no treatment <2 mo; age >18; Dutch	Phone inquiry (outcome, 5 pt. scale)	2–56 mo	13/35 complete relief; 11/35 improvement; 5/35 no relief but less of a problem	2,3,6
Horowitz (67)	N 29; age ?; SES ?, misc. ?	Intralesional interferon injections	Quasiexperimental clinical study	Pain at vaginal entry	No discharge, itching, or vulvar warts; Group 1 HPV; Group 2: no HPV	?	?	Group 1 (HPV) 15/17 complete relief, Group 2: 6/6 no relief	2,3,4,6

N, sample size; age, age range; SES socioeconomic status; misc. miscellaneous information.

* 1, no control/comparison group; 2, no random assignment; 3, nonblind treatment evaluation; 4, little information on sample selection procedures/sample characteristics not well defined; 5, heterogeneous sample; 6, no definition of therapeutic success.

[b] For whole sample as opposed to only for this treatment group.

fective than behavior therapy alone. However, treatment was not standardized, which limits the validity of the findings. Nonetheless, considering the noninvasiveness of psychological pain management therapies and their past success in the management of other chronic pain syndromes (69), these findings are promising.

In a recent study by Glazer et al. (55), 33 women with VVS underwent biofeedback training in order to reduce what was presumed to be a hypertonicity of their pelvic floor muscles. Sustained muscular hypertonicity has previously been hypothesized to produce ischemia and subsequently the release of pain-eliciting substances (70). After an average of 16 weeks of practice, 22 of the 28 women who were abstaining from intercourse at the beginning of the study resumed this activity, and 17 out of the 33 women in the sample reported pain-free intercourse. These initial results are very promising and require replication in a randomized controlled trial.

Secor and Fertitta (63) suggested acupuncture as a possible treatment for VVS, since it has been successful in the management of other chronic pain conditions. The application of cold is another option that is effective in the treatment of other types of pain and that is already being prescribed to soothe postoperative discomfort following vestibulectomy. It is also frequently mentioned by patients as an effective self-treatment that provides temporary relief of the pain (48).

SUMMARY AND FUTURE GUIDELINES FOR RESEARCH

The descriptive features of VVS have been primarily documented via clinical case studies. Although there is a definite need for epidemiological studies, the relative consistency of information presented in case studies and the corroborating evidence from controlled studies (e.g., 40) lend support to these reported descriptions.

Despite the fact that it is the central manifestation of VVS, pain symptomatology tends to be underemphasized in the current studies. More knowledge about pain characteristics (e.g., onset, temporal pattern, location, intensity) may also improve the reliability and validity of the diagnostic process. The present diagnostic criteria are subject to interpretation, as is shown by the different definitions of VVS and the varying selection criteria included in Tables 1 and 2. Recent data demonstrate that pain classification variables, more specifically the location and temporal pattern of the pain, as opposed to sexual dysfunction variables, are the best predictors of potential physical factors in the etiology of dyspareunia (e.g., 3). Nonetheless, we need more information about the impact of VVS on relationship adjustment and sexual functioning of patients and their partners.

Despite the extensive list of etiological factors that have been associated with VVS, there has been little progress in this area. This can be explained partly by the fact that VVS has only been recently recognized as a significant gynecological condition but also by the lack of methodologically sound etiological investigations. The omission of control groups (e.g., 5,7,8,19,24,27,42,44,45,47,58), small sample sizes (e.g., 7,19,27,44,47), unclear selection criteria and/or heterogeneous samples (e.g., 5,19,27,40) and unreliable measurement (e.g., 5,8,19,27,44,45) contribute to weakening the quality of the knowledge. Finally, cross-sectional designs do not allow for the differentiation between factors that are a result of the pain from those that may have contributed to its onset, maintenance, and exacerbation.

Another problem lies in the unidimensional approach usually adopted in designing the studies. The current trend in etiological studies is to focus on biomedical factors. However, concomitant organic pathology is rarely demonstrated and can, in fact, be viewed as an exclusion criterion to the diagnosis of VVS. Only a few etiological studies have adopted a nonreductionist approach (e.g. 3,27). As is suggested by many of the etiological hypotheses (hormonal, immunologic, etc.), VVS cannot be solely explained by local mechanisms. It is thus important to venture beyond unidimensional sensory-physiologic models of pain, which postulate that the pain experience is directly proportional to local tissue damage. In contrast, biopsychosocial models encompassing the role of psychological, behavioral, and sensory processes are more representative of the majority of pain syndromes (71) and are undoubtebly the most fruitful for the study of VVS.

One promising avenue of etiological research is the investigation of central pain mechanisms that may play a role in causing and maintaining VVS. The hypothesis that VVS may constitute sympathetically maintained pain (SMP) (e.g. 55,56) has received little direct empirical support and appears problematic, considering the numerous controversies surrounding the definition and validity of SMP (72–74). Nonetheless, this hypothesis has drawn the attention of the field toward the study of pain mechanisms, which had been hitherto overlooked.

Central mechanisms are thought to play a role in other types of acute recurrent gynecological pains such as dysmenorrhea (75), although there is still little knowledge concerning how information from the vulva and vagina arriving in the central nervous system is processed. Central factors may explain the reported success of pain management and sex therapy techniques in addressing the behavioral and cognitive components of pain.

As for peripheral processing mechanisms, there is growing experimental evidence from animal studies that visceral tissues exhibit an altered sensitivity in pathological conditions like inflammation, in such a way that "silent" afferents can become active (76). More specifically, mucosal afferents projecting through the pelvic nerve (which innervates the vaginal canal, the bladder, and the urethra, among other areas) that do not respond to noxious mechanical stimuli seem to be activated in inflammatory states (76). There is also evidence that inflammation of visceral organs can induce a similar altered sensitivity in the dorsal horn neurons of the spinal cord, a phenomenon referred to as central sensitization (76,77). Such changes in central neural function are thought to play a significant role in the development of pathological pain (77).

If indeed peripheral physiopathological states could bring on changes in the excitability of the CNS, leading to pain hypersensitivity, it could explain the seemingly unrelated associations of VVS with histories of candidiasis, condylomata infections, repeated urinary tract infections, and iatrogenic harm, all of which constitute pathological and/or injurious events occuring in the area of the vulva and vagina. Other proposed etiological mechanisms, such as weak immune functioning or hormonal factors, could contribute to further activation of the central nervous system of sensitized patients. This hypothesis serves a heuristic purpose in unifying some of the current etiological observations and highlights the need for human and animal research looking specifically into vulvar pain mechanisms.

The treatment of VVS has been a frustrating enterprise for all health professionals concerned, as none of the current options have brought about satisfactory results. Despite the fact that many gynecologists are reluctant to recommend surgical treatment of VVS, the majority of outcome studies pertain to this modality. Surgery is also the treatment option with the highest reported success rate. Medical management is underinvestigated, especially considering its widespread use. This may be due in part to clinical reports of its lack of efficacy. More recent, noninvasive pain management techniques such as biofeedback and behavior therapy show promising results. Furthermore, health care practitioners are beginning to reconceptualize the treatment of VVS in terms of long-term management (65), as is the case for other pain syndromes such as chronic low back pain. In addition, authors generally agree about the importance of providing patients with psychological support. At this point, there is a pressing need for prospective randomized clinical trials to provide systematic data into heretofore uncontrolled clinical observations.

In summary, a lack of emphasis on pain symptomatology is reflected in the descriptive, diagnostic, etiological, and treatment investigations conducted to date. More rigorous, multidisciplinary research efforts are needed in order to facilitate its proper investigation. Our review suggests that all aspects of research will benefit from a conceptualization of VVS as a localized pain syndrome. The adoption of a pain syndrome conceptualization will result in (a) descriptive studies investigating the central phenomenon, the pain; (b) more reliable diagnostic procedures; (c) a nonreductionist search for etiology; and (d) multimodal treatments focused on an episodic recurrent pain, all of which will broaden our insight into this prevalent women's health problem.

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Literature Review Update

During the period between June 1995 and November 1998, there has continued to be a proliferation of articles on vulvar vestibulitis, particularly in the gynecology literature. The syndrome is also gaining recognition in the sexology literature, as exemplified by its recent mention by two psychologist authors in a review of empirically validated treatments for sexual dysfunctions (Heiman & Meston, 1997). They suggest that the different types of disorders included under the heading of dyspareunia need further diagnostic differentiation and conceptualization in order to evaluate tailored treatments. This supports the research presented in this thesis.

There have been no new studies pertaining to the diagnosis of vulvar vestibulitis. In terms of etiology, one study has shown that the role of urinary oxalates as instigators of vulvar pain is doubtful, although they may constitute nonspecific irritants (Baggish, Sze, & Johnson, 1997). Two histopathological studies have demonstrated that women with vulvar vestibulitis have no more inflammatory cells in the vestibule than normal controls (Friedman, 1995; Nylander Lundqvist, 1997). Additionally, in this last study, participants all tested negative for human papillomavirus. However, Foster and Hasday (1997) found significantly more elevated levels of inflammatory cytokines in women with vulvar vestibulitis as compared to controls. Paradoxically, the cytokines were lowest in the area of highest hyperalgesia, the vulvar vestibule, and higher in the vulvar region. Finally, Weström and Willén (1998) found higher densities and numbers of nerve fibers in vestibular specimens of women with vulvar vesibulitis in comparison to vestibular specimens of controls. The number of controls was however much smaller than the number of cases. The authors' hypothesis concerning the etiological role of vestibular neural hyperplasia thus warrants further research.

Three studies were published regarding the psychosexual functioning of women with vulvar vestibulitis. White and Jantos (1998) reported that in comparison to

normative data, women with vulvar vestibulitis were more likely to have a reduced arousal potential and less interest in intercourse. Van Lankveld, Weijenborg, and Ter Kuile (1996) found that when compared to normative data, women with vulvar vestibulitis had more frequent problems with lubrication, arousal, and negative emotions in sexual interactions with their partners. They also had higher levels of somatization than norms, a finding similar to that of Jantos and White (1997), who noted that their cohort of patients with vulvar vestibulitis satisfied a number of somatization disorder criteria. These findings relating to somatization were not confirmed by Meana, Binik, Khalifé, & Cohen (1997), who compared their vulvar vestibulitis participants to normal matched controls. A more extensive investigation of somatization needs to be conducted before any firm conclusions can be drawn about its role in the development, maintenance and/or exacerbation of painful intercourse.

More studies were published on the topic of vestibulectomy (Bornstein, Goldik, Stolar, Zarfati, & Abramovici, 1997; Bornstein, Zarfati, Goldik, & Abramovici, 1995; Chaim, Meriwether, Gonik, Qureshi, & Sobel, 1996; Foster, Butts, Shah, & Woodruff, 1995; Goetsch, 1996; Kehoe & Luesley, 1996; Wolf, Abramov, Wolman, & David, 1995), demonstrating success rates equivalent to those reported in the critical review of the literature that serves as the introduction to this thesis (Bergeron, Binik, Khalifé, & Pagidas, 1997). Methodological problems were also the same as those mentioned in the review of the literature (chapter 1). Bornstein, Goldik et al. (1997) showed that women who have suffered from dyspareunia since their first intercourse attempt have lower success rates than women who have experienced a period of pain-free intercourse before developing vulvar vestibulitis.

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Transition Text 1

The critical review of the literature confirmed that vestibulectomy was the treatment modality with the highest success rates but that the studies evaluating its efficacy had numerous methodological problems, namely that treatment success was never clearly defined, that researchers rarely inquired about sexual functioning and pain, and that these studies were conducted by the surgeon who had performed the vestibulectomy. Considering the fact that we ultimately wanted to conduct a randomized treatment outcome study of vulvar vestibulitis that would include the current standard medical intervention, i. e., vestibulectomy, and that it was still a controversial procedure, we proceeded to perform our own study of the efficacy of vestibulectomy while correcting the methodological flaws of previous investigations. The following manuscript reports the results of this study.

The Surgical Treatment of Vulvar Vestibulitis Syndrome: A Follow-Up Study

SOPHIE BERGERON, CÉLINE BOUCHARD, MICHEL FORTIER, YITZCHAK M. BINIK and SAMIR KHALIFÉ

This study evaluated the effectiveness of vestibulectomy in relieving coital pain and improving sexual function in women diagnosed with vulvar vestibulitis. Vulvar vestibulitis syndrome, a chronic, nonspecific inflammation of the vulvar vestibule, probably represents the most frequent subtype of premenopausal dyspareunia. Participants were 38 women who underwent vestibulectomy at a university hospital between 1986 and 1994. Telephone interviews were conducted to assess whether vestibulectomy or other subsequent treatments affected coital pain and sexual functioning. Length of postoperative follow-up ranged from 1.1 to 10 years, with a mean of 3.3 years. Vestibulectomy yielded a positive outcome for 63.2% of the participants and moderate to no improvement for the other 36.8%. The surgery was linked to a significant increase in intercourse frequency for the entire sample and to an increase in oral and manual stimulation for the women with successful surgical outcomes. No other factors were significantly associated with treatment outcome.

Dyspareunia is the most common sexual complaint spontaneously reported to gynecologists,[1] with community prevalence rates estimated to be between 10% and 15%.[2,3] Dyspareunia is also the female sexual dysfunction most often associated with physical pathology.[4,5] It is characterized by genital pain experienced primarily during intercourse, although pain can also occur before or after coital activity. Its intensity can range from a mild discomfort to a sharp, burning pain, and it can be located

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anywhere from the external genitalia to the abdomen. Dyspareunia often causes marked distress and may be a factor of discord in intimate relationships, considering its significant impact on sexual functioning. (For an extensive review of the dyspareunia literature, see Meana and Binik.[6])

The only controlled empirical study pertaining to the description and etiology of dyspareunia revealed the existence of four distinct subtypes that differ on the basis of physical findings.[7] One of the subtypes, vulvar vestibulitis syndrome (VVS), is currently thought to be the main cause of dyspareunia in premenopausal women.[8,9] Moreover, this condition is highly prevalent, with reported rates of up to 15% in general gynecological practice.[10]

VVS was probably described over a century ago.[11,12] It is characterized by severe pain on vestibular touch or attempted vaginal entry, point tenderness to cotton-tip palpation of the vulvar vestibule, and physical findings confined to vestibular erythema.[13] Irritation and burning can persist for hours or days after sexual activity, and many patients also report localized pain from tampon use, finger insertion, and gynecological examinations.[14-16] Most of the women experiencing VVS are in their 20s and 30s and have typically consulted several health professionals before receiving the diagnosis. Approximately half develop coital pain after a period of pain-free intercourse, and for the other half, the pain has been present since their first intercourse experience.[8,10,17] Interference with intercourse and other sexual activities can range from mild to severe, with some couples avoiding all forms of sexual contact.

Although many etiological hypotheses have been proposed, current understanding of VVS is limited because most of the proposed causal explanations are derived from clinical case reports. This state of affairs is partly due to the fact that health professionals have only recently begun to recognize this condition as worthy of serious clinical and scientific attention. The trend in current etiological research is to focus on biomedical factors, such as repeated yeast infections (candidiasis), human papillomavirus, and hormonal factors, such as the early use of oral contraceptives.[17-21] In terms of psychological factors, women experiencing VVS report normal levels of relationship satisfaction and psychological adjustment.[8,16,22] However, relational and psychosexual factors may be involved in maintaining the pain. In recent reviews, we have proposed that a pain syndrome conceptualization taking into account the multidimensionality of the pain experience and incorporating biological and psychosocial factors is the most useful approach for the study and treatment of all types of coital pain.[23,24]

Despite limited knowledge, several treatments have been developed in an attempt to relieve the pain associated with VVS. Vestibulectomy has been the most investigated intervention to date,[24] with over 20 published studies evaluating its efficacy. This minor surgery, often referred to as modified perineoplasty, is usually recommended following the failure of medical management. It consists of an excision of the hymen and of all the sensitive areas of the vestibule, most frequently located in the posterior fourchette, to a depth of approximately 2 mm. The vaginal mucosa

is then sometimes mobilized and brought downward to cover the excised area.[13,25] This procedure is typically carried out as day surgery under general anesthesia. Women are instructed to gradually resume intercourse after approximately 6 to 8 weeks.[26,27] More recent studies have compared or presented minor variations in the surgical technique.[28,29]

There has been much controversy about using a surgical intervention to relieve coital pain due to VVS. Many factors have fueled this controversy, ranging from a lack of information about the nature of VVS to a reluctance to use an invasive, albeit common treatment. Despite the fact that most of the surgery outcome studies report success rates higher than 60%,[24] these results are weakened by multiple methodological flaws. Control groups are missing in most of the studies, pain measurement is rudimentary or not specified at all, length of follow-up is often quite short, and the therapeutic criteria for success are seldom clearly defined. Furthermore, standardized study protocols are rare; selection criteria for surgery are minimal, unclear, or unsystematic; and evaluation of treatment is always nonblind. Variation in surgical techniques creates another problem. In addition, the possible occurrence of other treatments during the period between the surgery and the follow-up inquiry is never mentioned, making it impossible to attribute the improvement in pain solely to the surgical procedure. Finally, the impact of vestibulectomy on sexual functioning has never been investigated.

One goal of the present study was to determine the suitability of including a vestibulectomy condition in a randomized treatment outcome study we were planning to conduct. Its primary advantages over previous studies are the following: (a) Assessment interviews were conducted by an independent researcher not associated with the surgeons; (b) the effect of vestibulectomy on sexual functioning was investigated; (c) therapeutic success, selection criteria, and study procedures were clearly defined; and (d) potential confounding treatments were taken into account. In summary, the goals of the study were to retrospectively evaluate the effectiveness of vestibulectomy in relieving coital pain and improving sexual functioning and to identify factors associated with postoperative outcome.

METHOD

Participants

Participants were 38 women who had undergone vestibulectomy at a university hospital between 1986 and 1994. The researchers were able to contact 53 of the 70 women who initially underwent vestibulectomy: 46 verbally agreed to participate, and 38 returned their signed consent form. At the time of the assessment interview, the majority of women were married (24.3%) or cohabitating with their partners (45.9%). Others were either dating one person (21.6%) or were single (8.1%). Most

participants were French Canadian (92.1%), a few were from other Canadian provinces (5.3%), and one was American (2.6%). The mean age was 28.2 years (range = 19–52). The mean level of education was 14.8 years of schooling (range = 10–19), which is equivalent to the second year of university.

Prior to surgery, all participants underwent colposcopy and had cervical cultures for gonorrhea and *Chlamydia*. After massage of the Bartholin glands, samples were taken at the duct openings for *Chlamydia trachomatis*, *Ureaplasma*, and *Mycoplasma* cultures. All active infections were treated. Patients included in the study met the following selection criteria: (a) the three VVS criteria (introital dyspareunia, point tenderness to a cotton-tip palpation of vestibular gland orifices, and physical findings confined to vestibular erythema), (b) moderate to severe interference with intercourse, (c) no active infections, (d) experience of VVS symptoms for a minimum of 6 months, and (e) failure of more conservative medical treatments (e.g., corticosteroid and anesthetic creams).

Materials and Procedure

Surgical Technique. Vestibulectomies were performed by one of three gynecologists (Céline Bouchard, Michel Fortier, or Samir Khalifé) in accordance with the following protocol: The hymen and all the sensitive areas of the vestibule, most frequently located in the posterior fourchette, were excised in a U-shape to a depth of approximately 2 mm. The vaginal mucosa was then mobilized if necessary, brought downward to cover the excised area, and sutured to the skin.

Telephone Interview Procedure. Women who underwent vestibulectomies between 1986 and 1994 were contacted by a nurse, who inquired about their interest in participating in a short, confidential telephone interview regarding their surgery. Consent forms were sent to the women who verbally agreed to take part in the study. Once a woman had returned her signed consent form, she was contacted by an independent research associate (Sophie Bergeron), who then proceeded to conduct a structured telephone interview comprising 36 questions pertaining to the outcome of the vestibulectomy, current pain during intercourse, other treatments, and sexual and couple functioning. The mean length of the interviews was 15 min.

The change in introital dyspareunia following the surgery was measured on a scale ranging from 1 (*no improvement*) to 5 (*complete relief*). Success was defined a priori as *significant improvement* (4) or *complete relief* (5). *Moderate improvement* (3), *little improvement* (2), and *no improvement* (1) ratings were categorized as unsuccessful outcomes.

RESULTS

Outcome of Vestibulectomy

Length of postoperative follow-up ranged from 1.1 to 10 years, with a mean of 3.3 years. On the basis of our a priori criteria, vestibulectomy

was successful for 63.2% of the women and unsuccessful for the other 36.8%. More specifically, 36.8% of participants reported complete relief of their pain, 26.3% reported a great improvement, 13.2% reported moderate improvement, 7.9% reported little improvement, and 15.8% reported no improvement. Of those who reported no improvement, one woman stated that her pain was worse as a result of the surgery. In addition, coital pain returned for 2 of the women who initially experienced complete relief of their pain and were considered successful outcomes. In one case, coital pain returned 6 months after surgery, and in the other pain returned $2^1/_2$ years later.

For 53.3% of the women who had a successful outcome, the length of time between their vestibulectomy and the complete relief or significant reduction of their pain was 2 to 4 months. For 13.3%, this period was less than 2 months, and for another 20.0% it was between 4 and 6 months, whereas for 13.4% over 6 months elapsed before they could consider the surgery to be a success.

Inquiry about pain characteristics following unsuccessful surgical outcome revealed that the level of pain was moderate, with a mean intensity of 3.0 on a scale of 1 to 5. Coital pain significantly interfered with intercourse for 27.3% of the women with unsuccessful outcomes, whereas other women reported less interference or none at all. The frequency of pain varied, with the majority of women (63.6%) not experiencing coital pain at every intercourse attempt.

Some participants reported having tried other means of alleviating their coital pain following the vestibulectomy. Among the women with unsuccessful outcomes, 3 were without pain at the time of the assessment interview. Two women attributed the relief of their pain to the fact that they discontinued the use of oral contraceptives, and another was cured by interferon injections. As for the women with successful surgery outcomes, 29.2% reported making minor changes in their sexual behavior (e.g., changing intercourse positions, prolonging sex play), 16.7% underwent some form of psychotherapy (individual, sex, or couple therapy, relaxation exercises, etc.), 4.2% tried alternative treatments (e.g., homeopathic remedies, acupuncture), 12.5% had other medical treatments (e.g., hormone replacement therapy), and 45.8% used some sort of cream or gel (e.g., lubricant jelly, anesthetic gel) at some point during the follow-up period.

Finally, 65.8% of participants said they would undergo the surgery again (among which were included 87.5% of the women with successful outcomes and 28.6% of the women with unsuccessful outcomes), whereas 23.7% would have preferred to try another treatment before the vestibulectomy, and 10.5% were not sure.

Impact of Vestibulectomy on Sexual Functioning

Paired-samples *t* tests were performed to evaluate the impact of vestibulectomy on sexual functioning (see Table 1). In the overall sample, the

TABLE 1
Sexual functioning

	Success (N = 24)			Failure (N = 14)			Entire sample (N = 38)		
Sexual behavior (per month)	Mean Before	Mean After	1-Tail Sig	Mean Before	Mean After	1-Tail Sig	Mean Before	Mean After	1-Tail Sig
Manual stimulation	3.31	6.31	0.01*	6.12	4.73	0.16	4.37	5.71	0.09
Oral stimulation	2.62	4.31	0.02*	5.12	4.18	0.20	3.57	4.26	0.14
Intercourse	3.63	7.68	0.04*	3.83	6.77	0.03*	3.71	7.31	0.01*
Masturbation	0.93	1.39	0.07	2.15	2.00	0.35	1.41	1.63	0.18

monthly frequencies of manual stimulation, oral stimulation, intercourse, and masturbation were higher in the 6 months preceding the assessment interview than in the 6 months preceding the surgery, although this difference was significant only for intercourse. Similarly, in the group of women with successful surgery outcomes, the postvestibulectomy frequencies of all sexual behaviors were higher than the prevestibulectomy frequencies, and this difference was significant for manual and oral stimulation as well as for intercourse. For the women with unsuccessful surgery outcomes, frequency of intercourse was also significantly higher after vestibulectomy. Taken together, these findings suggest that vestibulectomy has a general positive impact on sexual functioning.

Successful and unsuccessful outcomes were compared with independent-samples t tests for continuous variables and Mann-Whitney tests for categorical variables. Age, years of formal education, length of follow-up, and prevestibulectomy frequency of sexual activities (manual and oral stimulation, intercourse, and masturbation) did not differ significantly between the two groups. Women with successful and unsuccessful surgery outcomes also did not differ significantly with regard to marital status, prevestibulectomy relationship satisfaction, degree of support from partner, and confidence in treatment.

A second set of analyses was performed using a logistic regression model composed of variables that were not significantly correlated to one another, approached significance, or could plausibly be associated with outcome. The dependent variable was vestibulectomy outcome (successful vs. unsuccessful). The model included age, relationship satisfaction, and confidence in treatment. This model classified 71.9% of the cases correctly. However, it did not significantly predict outcome, $\chi^2(8, N = 32) = 12.9, p = .12$.

VVS Characteristics

The researchers' telephone interview included some general questions about VVS itself, such as the impact of the syndrome on the lives of the participants. All women stated that their coital pain had affected their sexual functioning, 73.7% stated that it had affected their relationship

with their partner, 60.5% felt that it had some effect on their mental health, and 42.1% felt it had some effect on their self-esteem. When asked about other family members experiencing dyspareunia, 25% of the women reported that they knew at least one female relative who had coital pain.

DISCUSSION

The results of the present study confirm the efficacy of vestibulectomy in relieving coital pain due to VVS. The surgical treatment of VVS was linked to a significant increase in intercourse frequency for women who underwent the surgery, independent of surgical outcome, and to a significant increase in manual and oral stimulation for women who had successful surgery outcomes. The vestibulectomy success rates found in this study are consistent with findings of other similar investigations and support the use of this surgery when less invasive treatments are unsuccessful. Furthermore, these results are in accordance with the observation that, compared with other treatments, this modality results in the best outcomes to date.[24] Despite the fact that certain health professionals still have reservations regarding the surgical treatment of VVS, there appears to be minimal surgical risk and minimal patient complaints following vestibulectomy. Unfortunately, our analyses did not enable us to identify potential predictors of outcome. This may be due in part to the lack of statistical power associated with our small sample and to the retrospective nature of the design.

Inquiring about the use of other treatments as well as having a longer follow-up period appear important, as they yielded a more detailed and comprehensive report of the efficacy of vestibulectomy. Considering that some study participants had used other methods to alleviate their pain following the surgery, it is possible that some of these measures (e.g., the use of lubricant jelly, relaxation exercises) contributed to the overall outcome. Nonetheless, it will be important to control for such effects in future studies. Also of interest is the reoccurrence of symptoms following the surgery, as happened in 2 out of 24 successful cases in this sample. A more conservative criterion might have resulted in these cases being classified as unsuccessful. In addition, this study shows that improvement in pain following vestibulectomy can sometimes take over 6 months.

The outcome data demonstrate that for the women who still experienced some coital pain following vestibulectomy, the intensity of their pain was moderate. Only 27.3% reported significant interference with intercourse. Furthermore, about half of the women did not experience pain at every intercourse attempt, suggesting that other psychosexual components may play a role in the experience of pain. These findings also illustrate the fact that the degree of improvement following vestibulectomy is continuous and that the reported outcome ultimately lies in the type of dependent measure or rating scale used.

Reports of participants regarding the impact of VVS on important aspects of their self-identity, such as their sexual functioning, their romantic relationships, and their self-esteem, testify to the fact that this

syndrome may cause significant distress and should alert health professionals to these patients' need for continued support. The finding that 25% of participants knew of a female relative experiencing dyspareunia is consistent with Goetsch's[9] report and may point toward the possibility of a genetic predisposition.

Although the present study has some of the same methodological problems common to other vestibulectomy investigations (retrospective, no control group), it constitutes a first step in integrating quantitative evaluation of pain and sexual functioning into outcome measures, as these two central aspects of VVS have been largely neglected by researchers and clinicians alike.[24] A randomized clinical treatment trial of the efficacy of vestibulectomy seems warranted, considering the consistency of our data with previous studies. One such trial is currently underway in our center.

Overall, the data are consistent with the notion that coital pain is a multifaceted syndrome comprising sensory, behavioral, interpersonal, and psychosexual aspects, which are probably best addressed by a multidimensional perspective based on a pain syndrome conceptualization.[25] To this effect, studies like that of Schover, Youngs, and Cannata[16] and Weijmar Schultz et al.[30] provide interesting means of improving current surgical treatments by combining them with sex therapy techniques, paving the way toward a multidisciplinary approach to the treatment of dyspareunia.

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Transition Text 2

In reviewing the vulvar vestibulitis literature, we found no studies on diagnostic reliability and validity. This led to some confusion in the interpretation of current diagnostic criteria, as demonstrated by the heterogeneous samples included in the studies published to date. Furthermore, there were little data concerning pain characteristics, although clinical case studies reported that the women often described their pain as a burning sensation. Since our follow-up study of vestibulectomy patients had confirmed the success of this intervention, we had decided to go ahead and conduct a randomized treatment outcome study of vulvar vestibulitis. The participant selection process of this randomized trial allowed us to examine a large number of women with different types of dyspareunia and to test them on two separate occasions before they received treatment. We used that opportunity to gather some data concerning the reliability of the vulvar vestibulitis diagnosis. We also wanted to assess the validity of current diagnostic criteria. The following manuscript reports the results of this study.

Vulvar vestibulitis syndrome: Reliability of diagnosis and validity of current diagnostic criteria

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Vulvar vestibulitis syndrome: Reliability of diagnosis and validity of current diagnostic criteria

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OBJECTIVES: The goal of this study was to assess the reliability of the diagnosis of vulvar vestibulitis and the validity of Friedrich's criteria for this diagnosis.

STUDY DESIGN: In a university hospital, 146 dyspareunic women underwent two sets of gynecological examinations, took part in a structured interview and filled out the McGill-Melzack Pain Questionnaire. Reliability was assessed using kappa and correlational analyses. Validity was examined using correlational and discriminant function analyses.

RESULTS: Inter-rater agreement and test-retest reliability ranged from moderate to substantial for the vulvar vestibulitis diagnosis. Of Friedrich's 3 criteria for vulvar vestibulitis, only *tenderness to pressure within the vulvar vestibule* differentiated between women with and without this condition. As for pain quality, 88.1% of vulvar vestibulitis participants chose adjectives referring to a thermal quality and 86.6% chose adjectives referring to an incisive pressure sensation.

CONCLUSIONS: Vulvar vestibulitis is a distinct clinical entity that can be reliably diagnosed.

Key Words: Vulvar vestibulitis, dyspareunia, vulvodynia, sexual pain disorder, diagnosis

Since Friedrich proposed the terminology in 1987[1], the diagnostic criteria for vulvar vestibulitis syndrome have been the following: (1) severe pain on vestibular touch or attempted vaginal entry, (2) tenderness to pressure localized within the vulvar vestibule, and (3) physical findings confined to vestibular erythema of various degrees. Despite the absence of studies regarding the diagnostic reliability and validity of these criteria, many researchers and clinicians implicitly or explicitly work with them, as they constitute the first attempt at formulating an operational diagnosis. However, Friedrich's definition has been subject to varying interpretations, leading to potentially heterogeneous samples in studies purporting to investigate vulvar vestibulitis.[2] In addition, many researchers have been using other diagnostic criteria such as erythematous vestibular lesions on colposcopy and nonspecific inflammation on histopathology, without evidence that these increase diagnostic reliability.[3,4] Another implicit criterion not currently operationalized is a minimum of six months' duration of the symptoms.[5]

Indeed, the present criteria may not be sufficient to differentiate vulvar vestibulitis from other vulvar and coital pain syndromes. For example, vestibular erythema are a common symptom of many types of vulvar inflammation and there is no empirical evidence that they distinguish vulvar vestibulitis from other vulvovaginal conditions. The term *tenderness to pressure* does not seem to accurately reflect the thermal sensation or the severe pain that many women with vulvar vestibulitis report during the cotton-swab test. In addition, the first criterion lacks in clarity as it fails to differentiate between vestibular touch and attempted vaginal entry. These constitute distinct activities that usually correspond to two different measures of pain, one being the cotton-swab test and the other, a self-report of pain intensity during attempted intercourse. In fact, the extent to which these two reports of pain correlate is unknown. The purposes of this study were thus to assess a) the reliability of the vulvar vestibulitis diagnosis as defined by Friedrich, b) the validity of Friedrich's diagnostic criteria, and c) the usefulness of these criteria in the diagnostic process.

Material and Methods

Participants were 146 dyspareunic women recruited between January and July 1996 through local media announcements and professional referrals. Potential subjects were screened over the telephone by a trained clinical associate. If interested, women were interviewed at the Department of Obstetrics and Gynecology of a university hospital, where study procedures were explained and informed consent was obtained. Women not meeting the selection criteria were referred appropriately. This study protocol was approved by the McGill Institutional Ethics Review Board.

Participants in the study met the following inclusion criteria: 1) pain during intercourse which is a) subjectively distressing, b) occurs(ed) on most intercourse attempts, and c) has lasted for at least six months; women who stopped attempting intercourse as a result of the pain were included if the pain could be confirmed during the gynecological examinations or through a recent attempt at intercourse. Exclusion criteria were the following: 1) pelvic or vaginal pain not clearly linked to intercourse; 2) a history of remitted coital pain; 3) presence of one of the following: a) major medical and/or psychiatric illness, b) active infection, and c) vaginismus; 5) ongoing treatment for coital pain; 6) pregnancy; 7) age less than 18 or greater than 50.

Participants took part in a structured interview administered by a trained clinical associate. The interview covered socio-demographic information, medical history, and a detailed description and history of coital pain and other possible vulvar/pelvic pain, including a self-report measure of painful intercourse and the McGill-Melzack Pain Questionnaire.[6] This adjective check list is a widely used, reliable and valid measure of both qualitative and quantitative aspects of pain.

On the first visit, each woman underwent two independent gynecological examinations carried out according to the following standardized protocol: 1) a urine sample was obtained from each patient; 2) a brief interview about past medical history, medication, and obstetrical/gynecological history, including painful intercourse, was

conducted by the gynecologist performing the first examination; 3) vaginal cultures were taken for *Candida*, *Gardnerella* and *Trichomonas*, as well as a Pap smear if the patient had not been tested in the past year; 4) a cotton-swab palpation of the following vulvar areas was carried out: a) labia majora and labia minora (right, left and midline), and six vestibular sites (in a clockwise fashion: 12 o'clock, then 12 to 3, 3 to 6, 6, 6 to 9, and 9 to 12 o'clock); 5) the degree of vestibular erythema was evaluated by each gynecologist on a scale of 0 (none) to 3 (severe) and noted on a standardized form; 6) a standard bimanual palpation of the following areas was carried out: vagina (anterior vaginal wall, pubococcygeal muscle, uterosacral ligament, insertion of speculum, insertion of finger), uterus (cervix and corpus with and without motion), and adnexae (with and without motion). Patients rated the pain at each site on a scale of 0 (no pain) to 10 (worst pain ever); a research assistant recorded patients' pain ratings on a standardized form for all of the above-mentioned sites. In addition, any other physical findings were noted, as were the gynecologists' final diagnoses.

Gynecologists were instructed to use Friedrich's criteria as best they could to diagnose vulvar vestibulitis syndrome. These criteria were stated as follows: 1) pain limited to intercourse and other activities involving vestibular pressure (e.g. bicycling); 2) moderate to severe pain in one or more locations of the vestibule during the cotton-swab test; 3) presence of vestibular erythema.

All participants were asked to remain untreated and to discontinue use of potential allergens (e.g. perfumed soaps) for a minimum of six weeks, at which point they were scheduled for two additional gynecological examinations, identical to the initial ones and done independently by the same gynecologists. The order of gynecologists carrying out the examination at time 1 was reversed at time 2. At this second appointment, participants were informed of examination results.

Statistical analyses were conducted by examining: 1) the relationship between socio-demographic variables (age, income, educational level, birthplace, religion, marital

status, parity, language of interview) and dependent measures (pain and physical findings); 2) the reliability of the gynecologists' vulvar vestibulitis diagnoses (kappa); 3) the validity of Friedrich's three diagnostic criteria (Pearson product moment correlations, Spearman rank order correlations, kappa, and descriptive statistics) and their usefulness in diagnosis (discriminant function analyses).

Results

One-hundred two out of a total of 146 participants completed all the medical and psychosocial testing. Twenty-six women dropped out of the study after the first set of gynecological examinations and eighteen were not tested a second time by one of the gynecologists. Five women did not complete the structured interview. The women who dropped out of the study were not significantly different from the remaining participants on any of the demographic or pain variables.

Sample demographics. The following demographic information is based on the 141 participants who completed the gynecological testing and interviews at time 1. The mean ± SD age of the participants was 27.7 ± 6.3 years (range 19 to 50). One hundred twenty (85.1%) were born in North America, 9 (6.4%) in Europe, 5 (3.5%) in Latin/South America, and 7 (5.0%) on other continents. Language of interview was French for 87 (61.7%) women and English for 54 (38.3%). Household annual income was between 0 and 19,999$ for 65 (46.1%) women, between 20 and 39,999$ for 29 (20.6%), between 40 and 59,999$ for 19 (13.5%), and over 60,000$ for 28 (19.9%). The mean ± SD number of years of schooling was 16.1 ± 2.9. Seventy-four (52.5%) participants were Catholic, 9 (6.4%) were Protestant, 9 (6.4%) were Jewish, 5 (3.5%) practiced another religion, and 44 (31.2%) did not identify with any religion. Twenty-one (14.9%) were married, 49 (34.8%) were living with their partner, 40 (28.4%) were regularly dating a partner, and 31 (22%) did not have a regular partner. Thirteen (9.2%) women had experienced childbirth. The mean ± SD duration of the coital pain problem

was 66.3 ± 62.9 months. None of the socio-demographic variables were significantly associated with our dependent measures.

Reliability of the diagnosis of vulvar vestibulitis. At the first set of gynecological examinations (time 1), both gynecologists agreed on the diagnosis of vulvar vestibulitis for 126 women and on another pain or non-pain related problem for 11 women. They could not agree on a diagnosis for nine women. The percentage agreement between the two gynecologists for the diagnosis of vulvar vestibulitis versus other diagnoses (one single category including all non-vulvar vestibulitis diagnoses) was 93.8%, yielding a kappa of 0.68. At the second set of examinations (time 2), 98 women were diagnosed by both gynecologists with vulvar vestibulitis, two were diagnosed with another pain or non-pain related problem, and two could not be reliably diagnosed. The percentage agreement at time 2 was 98.0%, yielding a kappa of 0.66. In terms of test-retest reliability, the percentage agreements between times 1 and 2 for each of the gynecologists were respectively 96.7% (k=0.49) and 93.9% (k=0.54).

In addition, both gynecologists agreed that 34.1% (N=43) of women diagnosed with vulvar vestibulitis at time 1 also had deep pelvic pain. This subset of women was not significantly different from the women with only vulvar vestibulitis on any of the pain or demographic variables except for two scales of the McGill-Melzack Pain Questionnaire (evaluative and miscellaneous). Women diagnosed with vulvar vestibulitis and deep pain were therefore excluded from analyses pertaining to this questionnaire. Otherwise, the following analyses involve participants diagnosed with vulvar vestibulitis only as well as those with vulvar vestibulitis and concomitant deep pain.

Reliability and validity of Friedrich's three diagnostic criteria. The following analyses are based on the sample of 126 women diagnosed with vulvar vestibulitis by both gynecologists at time 1.

(1) Severe pain on vestibular touch or attempted vaginal entry. Pain on attempted vaginal entry was an inclusion criterion for this study and was documented by a one

time patient self-report of typical pain during intercourse on a scale of 0 (no pain) to 10 (worst pain ever). The median pain rating was 7.0. Aside from presenting with dyspareunia (*severe pain on...attempted vaginal entry*), women suffering from vulvar vestibulitis reported experiencing pain associated with a number of activities, sexual and other (*severe pain on vestibular touch*) (see Table I). Excluding the subset of women with concomitant deep pelvic pain, a qualitative description of the pain was obtained based on the McGill-Melzack Pain Questionnaire adjectives: 88.1% of the participants chose adjectives that described a *thermal* quality (hot, burning, scalding, or searing) and 86.6% chose adjectives that described *incisive pressure* (sharp, cutting, or lacerating).

(2) Tenderness to pressure localized within the vulvar vestibule. Patient pain ratings from each of the four gynecological examinations were averaged for every vestibular palpation site. Mean ratings ranged from 2.45 at the 12 o'clock site to 7.58 at the 9 to 12 o'clock site. These mean patient pain ratings were then correlated (Spearman's correlation coefficient) between gynecologists' examinations at both times 1 and 2. Although the means from one gynecologist's examinations (K. P.) tended to be lower, all pain ratings were significantly correlated (see Table II). In addition, using paired-samples t-tests, participants' mean pain ratings were compared within gynecologists; no significant differences were found between participants' mean pain ratings at times 1 and 2 for either of the gynecologists. In terms of the pattern of the pain, the mean pain ratings were lower at 12 o'clock for all exams and the mean 12 to 3 o'clock ratings were the second lowest rating of each exam. Vestibular pain did not otherwise exhibit a specific pattern. The most painful areas encompassed the 3 to 6, 6, 6 to 9 and 9 to 12 o'clock areas. After averaging the participants' six vestibular pain ratings per examination, we analyzed the four distributions and found that they were all normally distributed, with 52.1% to 71.2% of cases falling between 4.5 and 7.5.

Pain in the areas of the labia majora and labia minora was minimal for both sets of exams, with mean patient pain ratings for these areas ranging from 0 to 1.49 (see Table

II). Within this limited range of pain intensity, ratings were significantly higher for the labia minora than for the labia majora (Wilcoxon, $p < 0.00001$). More specifically, 79.5% of participants did not report pain in the labia majora at any of the 4 gynecological examinations, whereas only 15.5% of participants never reported pain in the labia minora. When results of the four examinations were collapsed together, the mean pain rating for the labia minora was 1.0.

In order to examine the degree of association between Friedrich's criteria 1 and 2, we collapsed the participants' six vestibular pain ratings for each gynecologist's set of examinations to form two indices of vestibular pain (criterion 2). These indices were then correlated with the measure of self-reported pain during intercourse on a scale of 0 to 10 (criterion 1); this yielded an r of 0.28 ($p < 0.01$) for S. K. and an r of 0.04 (p not significant) for K. P.

(3) Physical findings confined to vestibular erythema of various degrees. Comparison of the two gynecologists' erythema ratings (Spearman's correlation coefficient) revealed an r of 0.06 (p not significant) at time 1 and an r of -0.04 (p not significant) at time 2. As for test-retest reliability, comparison between times 1 and 2 for each doctor resulted in correlations of 0.11 (p not significant) and 0.23 ($p < 0.02$). In order to explore further the degree of inter-rater agreement, erythema ratings were recoded to form only two categories, i. e., presence or absence of erythema, and kappa analyses were performed. Results show that the percentage agreement between the two gynecologists at time 1 was 59.8%, yielding a kappa of 0.12, and that the percentage agreement at time 2 was 83.3%, yielding a kappa of -0.08. The percentage agreements between times 1 and 2 for each of the gynecologists were respectively 64.2% (k=0.10) and 33.3% (k=-0.13).

Relationship between Friedrich's criteria and classification. Stepwise discriminant function analyses were conducted to test up to what point Friedrich's three diagnostic criteria were effective in discriminating participants who were suffering from

vulvar vestibulitis from those who were not. Although there is a large size difference between these two categories, prior probabilities were assumed to be equal in the classification analysis in order to have a conservative measure of significance. *Tenderness to pressure within the vulvar vestibule* was operationalized by averaging the six patient vestibular pain ratings (cotton-swab test) to form one index of vestibular pain per examination. Erythema was recoded as present or absent. The discriminant function analysis for the first gynecologist's examinations at time 1 resulted in one significant function [$\chi^2(1, N=117)=50.50, p < 0.00001$] in which only the *tenderness to pressure within the vulvar vestibule* criterion was included. The classification analysis indicated that 90.4% of cases were correctly classified. The discriminant function for the second gynecologist's examinations at time 1 yielded one significant function [$\chi^2(2, N=87)=58.48, p < 0.00001$] in which both the *tenderness to pressure within the vulvar vestibule* and the *attempted vaginal entry* criteria were included, resulting in 92.5% of the cases being correctly classified. The discriminant function for the first gynecologist's examinations at time 2 yielded one significant function [$\chi^2(1, N=107)=13.23, p < 0.0005$] in which only the *tenderness to pressure within the vulvar vestibule* criterion was included. The classification analysis indicated that 89.7% of cases were correctly classified. Finally, the discriminant function for the second gynecologist's examinations at time 2 also yielded one significant function [$\chi^2(2, N=15)=5.21, p < 0.05$] in which only the *tenderness to pressure within the vulvar vestibule* criterion was included, classifying 91.7% of cases correctly.

Comment

The results of the present study are the first to demonstrate that vulvar vestibulitis syndrome constitutes a clinical entity that can be reliably diagnosed. This is supported by the substantial inter-rater agreement between the two gynecologists at both times 1 and 2 and by the moderate test-retest reliability.[7] The observed discrepancy between the

percentage agreement figures and the kappa values is due to the high sensitivity of the kappa statistic to the number of categories[8] and to the proportions of true positive and true negative cases in the sample.[9] In the current study, the high frequency of the vulvar vestibulitis diagnosis contributed to lower the kappa values. Reliability findings obtained from samples with different base rates may not be comparable.[9]

Findings from the McGill-Melzack Pain Questionnaire show that 88.1% of vulvar vestibulitis participants chose adjectives that described a thermal quality and 86.6% chose adjectives that described an incisive pressure sensation. These results demonstrate that there is a remarkable consistency in the pain descriptions of women with vulvar vestibulitis. They also corroborate clinical accounts which often describe a burning pain; however, an *incisive pressure* sensation had never been previously documented. Pain quality reports are important in the diagnosis and classification of pain and may be very useful in distinguishing between different genital and pelvic pain syndromes.

Although patient pain ratings from the cotton-swab test were significantly correlated between gynecologists for each of the vestibular and labial palpation sites, they tended to differ depending on which gynecologist conducted the exam. The vestibular patient pain ratings based on one gynecologist's examinations (K. P.) were often lower than those elicited by the other gynecologist. This difference appears to result from the differing degrees of pressure applied by each gynecologist and was the source of disagreement for the majority of cases that could not be reliably diagnosed. Use of an algesiometer or Von Frey hairs may solve this problem (e.g. 10). Nonetheless, average patient vestibular pain ratings were not significantly different from time 1 to time 2. Taken together, these results show that the cotton-swab test involving patient pain ratings is a reliable measure of pain that should be used in future outcome studies. Furthermore, results from the discriminant function analyses support the discriminant validity of this measure.

Our data confirm that pain due to vulvar vestibulitis is limited to the vulvar vestibule and that consequently, pain within the labia majora and labia minora is generally non-existent. This is illustrated by the fact that 79.5% of the women did not report pain in the labia majora at any of the 4 gynecological examinations. In contrast, 84.5% reported pain in the labia minora, although the mean pain rating was very low. These findings may serve to distinguish vulvar vestibulitis from chronic vulvar pain syndromes where pain may be felt in the entire vulvar area.

Despite the fact that the mean pain ratings were lowest at the 12 o'clock and 12 to 3 o'clock sites, vestibular pain did not otherwise exhibit a specific pattern. This is contrary to what has been anecdotally mentioned in the literature,[11, 12] where pain has been reported to be worse between 4 and 8 o'clock or in the region of the Bartholin glands (posterior fourchette). The fact that the 12 to 3 o'clock area was generally less painful than the 9 to 12 o'clock region may be explained by the clockwise pattern of the cotton-swab examination. Future studies and clinical examinations should counterbalance the order of palpation in the cotton-swab test.

The averaged vestibular patient pain ratings were normally distributed for each of the gynecological examinations. Similarly, Goetsch[11] found that swab sensitivity occurred along a continuum. These findings suggest that the pain of vulvar vestibulitis is best represented as a continuum and that categorical diagnostic boundaries based solely on the cotton-swab test may be somewhat arbitrary. Future studies using the cotton-swab test for selection of participants should thus adopt an a priori cut-off point for patient pain ratings.

We found that there is only a weak relationship between self-reported pain during intercourse and patient pain ratings taken during the cotton-swab test. A low correlation between laboratory and function measures of pain is common to many chronic pain syndromes.[13] From a biopsychosocial perspective, this weak relationship can also be partly explained by the fact that an intimate sexual relationship and a gynecological

examination are two very distinct situations associated with different interpersonal and emotional cues. In addition, our measure of self-reported pain during intercourse is retrospective and represents an average over time (last six months); perhaps the use of a daily pain monitoring diary would provide a better estimate of the relationship between these two measures of pain. Our results also point to the importance of clarifying Friedrich's first criterion which includes both *vestibular touch* and *attempted vaginal entry*. Finally, the weak association between self-reported pain during intercourse and cotton-swab test pain ratings suggests the need to include both outcome measures in future clinical trials.

Inter-rater agreement and test-retest reliability for the presence or absence of erythema were poor[7], suggesting that despite the fact that it is one of Friedrich's three diagnostic criteria, it may not significantly contribute to diagnostic decision-making. This conclusion was further supported by the results of discriminant function analyses, which revealed that *tenderness to pressure within the vulvar vestibule* was the only criterion that differentiated between women who were diagnosed as having vulvar vestibulitis and those who were not. Additional support is also provided by Friedman[14] and Moyal-Barraco et al.,[15] who found that normal controls were not significantly different from vulvar vestibulitis women in terms of the presence of erythematous lesions.

The diagnostic procedure used in this study contrasts with that of other authors[4, 16] who typically require erythematous vestibular lesions on colposcopy and nonspecific inflammation on histopathology to make their vulvar vestibulitis diagnosis. Colposcopies were not performed here because our previous research suggested that this examination did not add new information.[17, 18] Furthermore, when comparing the pathological results of vestibular biopsies taken from asymptomatic women to those taken from patients with vulvar vestibulitis, both Friedman[14] and Nylander Lundqvist[19] found the same histopathological changes in both groups, namely nonspecific

inflammation. These findings taken with those of the present study suggest that the presence of erythematous lesions and/or inflammation are not necessary diagnostic indicators.

Based on the findings of this study, *moderate to severe pain during attempted penetration* and *moderate to severe pain limited to the vulvar vestibule as confirmed by a cotton-swab test* appear to be the two main diagnostic criteria for vulvar vestibulitis. Additionally, *pain experienced as a thermal and/or an incisive pressure sensation* is described by a majority of women with vulvar vestibulitis and thus merits diagnostic consideration. Future studies are needed to provide additional validation of these proposed criteria and to shed more light on the complex array of factors that contribute to cause and maintain this frustrating recurrent pain syndrome.

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This article stands in partial fulfillment of Ms. Bergeron's PhD requirements.

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Table I. Percentage of women diagnosed with vulvar vestibulitis reporting pain in other situations

	N	%
Standard gynecological exam	99	90.0
Urination after intercourse	71	80.7
Finger insertion	78	72.9
Tampon insertion	50	65.8
Tampon removal	49	64.5
Partner manual stimulation	51	46.8
Friction with clothing	38	34.9
Sporting activity	22	20.0
Urination in general	20	18.2
Partner oral stimulation	15	14.3
Masturbation alone	15	14.3
Other activity	6	5.5

Table II. Vulvar vestibulitis women's mean vulvar pain ratings

	Time 1			Time 2		
Site (clockwise)	S. K.	K. P.	r^a	S. K.	K. P.	r^b
Vestibule						
12 o'clock	2.45	2.89	0.35**	2.45	2.52	0.42**
12 to 3 o'clock	6.41	4.52	0.39*	6.06	4.96	0.60*
3 to 6 o'clock	7.55	5.61	0.43*	7.35	5.87	0.58*
6 o'clock	7.30	5.81	0.39*	6.92	6.25	0.57*
6 to 9 o'clock	7.55	6.46	0.45*	7.35	6.79	0.62*
9 to 12 o'clock	7.58	6.43	0.38*	7.24	6.95	0.64*
Labia						
majora right	0.00	0.19	-	0.01	0.20	0.37††
majora left	0.00	0.21	-	0.01	0.06	0.44†
majora midline	0.00	0.16	-	0.01	0.23	0.35††
minora right	0.61	1.30	0.44*	0.88	1.47	0.43†

minora left	0.55	1.28	0.09	0.91	1.49	0.36††
minora midline	0.84	1.38	0.42*	1.08	1.38	0.33††

*p<.00001, **p<.0002, †p<.0001, ††p<.001

a. Spearman rank order correlations between S.K. and K.P. patient self-report pain ratings: time 1.

b. Spearman rank order correlations between S.K. and K.P. patient self-report pain ratings: time 2.

Transition Text 3

As mentioned in Transition Text 2, based on the positive results of the vestibulectomy follow-up study, we decided to conduct a randomized treatment outcome study that would include this surgical intervention. Our review of the literature as well as our biopsychosocial approach led us to become interested in two other treatments that appeared most promising, i.e., surface electromyographic biofeedback and cognitive-behavioral therapy focusing on sexual functioning and pain. We chose to administer the three treatments separately as opposed to comparing treatment combinations because none of these interventions had yet been tested in a randomized trial. We thus wanted to investigate the efficacy of each treatment modality on its own, as well as to assess how each performed in comparison to others. We were particularly interested in evaluating the success rates of each of the two behavioral treatments in comparison to the vestibulectomy, the standard medical intervention for vulvar vestibulitis. The following manuscript reports the results of this study.

Running head: RANDOMIZED TREATMENT OUTCOME STUDY OF DYSPAREUNIA

A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis

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Abstract

This study compared group cognitive-behavioral therapy, electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis. Subjects were 78 women randomly assigned to 1 of 3 treatment conditions and assessed at pretreatment, posttreatment and 6-month follow-up via gynecological examinations, structured interviews and standard questionnaires pertaining to pain, sexual function, and psychosocial adjustment. As compared with pretreatment, all treatment groups reported statistically significant reductions on pain measures at posttreatment and 6-month follow-up, although the vestibulectomy group was significantly more successful than the 2 other groups. All 3 groups significantly improved on measures of psychological adjustment and sexual function from pretreatment to 6-month follow-up. Results suggest that women with dyspareunia can benefit from both medical and behavioral interventions.

Chronic or recurrent pain involving the female reproductive system is a neglected, poorly understood, and costly women's health problem. Chronic pelvic pain is at the source of 25% of laparascopies performed annually in the U.S. and is the third leading indication for hysterectomy (Walling & Reiter, 1995). Dyspareunia, or painful intercourse, a recurrent acute pain, affects 10 - 15% of women in North America (Laumann, Gagnon, Michael, & Michaels, 1994; Walker et al., 1991). In addition to disrupting sexual relations, dyspareunia impacts negatively on relationship adjustment and general psychological well-being (Bergeron, Bouchard, Fortier, Binik, & Khalifé, 1997; Meana, Binik, Khalifé, & Cohen, 1997a).

Within the mental health domain, the challenging task of treating dyspareunia has usually been left to cognitive-behaviorally oriented therapists interested in sexuality and/or pain. Typical interventions aim at reducing the pain and improving sexual function; they include Kegel exercises, systematic desensitization, vaginal dilatation, and relaxation (Lazarus, 1989; Meana & Binik, 1994). More specifically, cognitive-behavioral sex therapy techniques are thought to reduce the conditioned fear of pain and the lack of arousal associated with painful intercourse. They can be delivered in individual, couple, or less frequently, group format. Group cognitive-behavioral therapy for pain is usually as effective as individual therapy (Turk, Meichenbaum, & Genest, 1983). In terms of treatment outcome, there have only been two retrospective studies conducted with a population of premenopausal women, and these show that 43 to 68% of women who undergo individual behavioral sex therapy treatments benefit from a significant improvement or complete relief of their pain (Abramov, Wolman, & David, 1994; Weijmar Schultz et al., 1995). However, neither of these treatments were standardized, which limits the validity of the findings.

Surface electromyographic (sEMG) biofeedback has also been used successfully in the treatment of various chronic pain syndromes (e.g. headaches) but has only recently been adapted for the specific purpose of reducing dyspareunia. Glazer, Rodke,

Swencionis, Hertz, & Young (1995) were the first to demonstrate that sEMG biofeedback is effective in relieving painful intercourse. In their uncontrolled study, 33 women suffering from different types of vulvar pain underwent sEMG biofeedback training in order to reduce the instability and hypertonicity of their pelvic floor muscles. Sustained muscular hypertonicity has previously been hypothesized to produce ischemia and subsequently the release of pain-eliciting substances (Flor & Turk, 1984). After an average of 16 weeks of practice, 22 of the 28 women who were abstaining from intercourse at the beginning of the study resumed this activity, and 52% of the women in the entire sample reported pain free intercourse. In reviewing the currently available non-medical interventions for dyspareunia, Heiman and Meston (1997) concluded that mental health professionals cannot claim efficacious treatments.

As is the case for other sexual problems such as erectile dysfunction, painful intercourse has not solely been the domain of psychology and psychiatry. Indeed, dyspareunia is the most common sexual complaint spontaneously reported to gynecologists (Steege, 1984). Although the somatic treatments traditionally prescribed by physicians (e.g. topical ointments, oral medications, surgery, etc.) have not been adequately empirically validated, the lack of proven efficacy of psychological interventions and the growing field of medical and pharmacological treatments for sexual dysfunction (e.g. Viagra for erectile difficulties and selective serotonin reuptake inhibitors for premature ejaculation) have led to a renewed interest in medical approaches. As a result, the current state of affairs for many women suffering from dyspareunia is that they are referred back and forth between gynecologists and mental health professionals, who provide conflicting rationales and advice concerning intervention. Apart from a few exceptions, (e.g. Schover, Youngs, & Cannata, 1992), multidisciplinary approaches involving health care practitioners from different backgrounds are rare. There is thus clearly a need for systematic comparative outcome studies of the different interventions in order to guide clinical recommendations in the treatment of dyspareunia.

Part of the delay in treatment evaluation can be attributed to conceptual difficulties. Dyspareunia has traditionally been viewed as a unitary syndrome with the only classification distinctions lying in broad, dichotomous descriptors such as historical, situational, and organic/psychogenic variables. This has led it to be conceptualized alternatively as a sexual dysfunction, a psychosomatic gynecological problem, and a pain syndrome (Lynch, 1985; McKay, 1989; McKay, 1992; Meana & Binik, 1994; Rosen & Leiblum, 1995), although none of these characterizations were based on scientific evidence. However, a recent empirical study shed some light on this conceptual issue by demonstrating the existence of several distinct subtypes that differ on the basis of physical findings (Meana, Binik, Khalifé, & Cohen, 1997b). The most common of these subtypes is thought to be vulvar vestibulitis syndrome, a condition characterized by a sharp, burning pain located within and limited to the vulvar vestibule (vaginal entry) and elicited primarily via pressure applied to the area. This distressing syndrome affects mostly young women and has no clear etiological determinants, although it has been associated with repeated yeast infections and other urogenital inflammatory conditions (Bergeron, Binik, Khalifé, & Pagidas, 1997; Marinoff & Turner, 1991; Peckham, Maki, Patterson, & Hafez, 1986). Diagnosis is made during a gynecological examination with the cotton-swab test, a procedure during which the physician applies pressure to different points all around the vestibule; both test-retest and inter-rater reliability have been shown to be very good (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 1998). With a prevalence rate of 15% in general gynecologic practice (Goetsch, 1991), vulvar vestibulitis is currently considered the main cause of dyspareunia in premenopausal women (Friedrich, 1988; Meana et al., 1997a) and is gaining considerable attention in the gynecology literature.

Along with attempts to relieve the pain via various topical applications, gynecologists developed a surgery designed to excise the painful tissue in the vulvar vestibule. Although still a controversial procedure, vestibulectomy is becoming a frequently recommended

surgical intervention and has been the most investigated treatment for vulvar vestibulitis, with over 20 published studies, albeit retrospective, evaluating its efficacy. The presumed rationale underlying vestibulectomy is that the removal of damaged nerve endings located in the painful area will result in complete eradication of the pain. This procedure, first proposed by Woodruff and Parmley (1983), is typically carried out as day surgery under general anesthesia and lasts about 30 minutes. Although success rates range from 43 - 100%, with the majority of estimates surpassing the 60% mark, these conclusions are weakened by multiple methodological flaws (Bergeron et al., 1997).

Although vestibulectomy is fast becoming the most recommended treatment for vulvar vestibulitis syndrome, there is no firm knowledge as to whether it meets optimal standards of care. Furthermore, its invasiveness may not appeal to a majority of patients. It is conceivable that non-invasive behavioral treatment modalities could provide comparable outcomes without the inherent risks and disadvantages of a surgical procedure. As such, they would represent a much needed alternative to vestibulectomy.

The purpose of the present study was thus two-fold: 1) to prospectively evaluate and compare the differential efficacy of group cognitive-behavioral therapy (GCBT), sEMG biofeedback, and vestibulectomy in relieving dyspareunia as well as improving sexual function and psychosocial adjustment; 2) to contribute to the empirical validation of cognitive, behavioral, and medical interventions in the treatment of dyspareunia.

Method

Participants

Participants were 87 women suffering from vulvar vestibulitis. They were selected from a pool of 168 dyspareunic women recruited between January and July 1996 through local media announcements and professional referrals. As part of the selection process,

potential participants were screened over the telephone by a trained clinical associate. If interested, women were interviewed and examined at the Department of Obstetrics and Gynecology of a university hospital, where study procedures were explained and informed consent was obtained. This study protocol was approved by our institution's ethics review board.

Participants in the treatment study met the following inclusion criteria: 1) pain during intercourse which is a) subjectively distressing, b) occurs(ed) on most intercourse attempts, and c) has lasted for at least six months; women who stopped attempting intercourse as a result of the pain were included if the pain could be confirmed during the gynecological examinations or through a recent attempt at intercourse; 2) pain limited to intercourse and other activities involving vestibular pressure (e.g. bicycling); 3) moderate to severe pain in one or more locations of the vestibule during the cotton-swab test (cf Procedure); this was operationalized as a minimum average patient pain rating of 4 on a scale of 0 to 10. Exclusion criteria were the following: 1) pelvic or vaginal pain not clearly linked to intercourse; 2) a history of remitted dyspareunia; 3) presence of one of the following: a) major medical and/or psychiatric illness, b) active infection, and c) vaginismus; 5) ongoing treatment for dyspareunia; 6) pregnancy; 7) age less than 18 or greater than 50.

Procedure

On the first visit, each potential participant underwent two independent gynecological evaluations carried out according to the following standardized protocol: 1) a urine sample was obtained from each patient; 2) a brief interview about past medical history, medication, and obstetrical/gynecological history, including painful intercourse, was conducted by the gynecologist performing the first examination; 3) vaginal cultures were taken for *Candida*, *Gardnerella* and *Trichomonas*, as well as a Pap smear if the patient had

not been tested in the past year; 4) a cotton-swab palpation of the following vulvar areas was carried out: a) labia majora and labia minora (right, left and midline), and six vestibular sites (in a clockwise fashion: 12 o'clock, then 12 to 3, 3 to 6, 6, 6 to 9, and 9 to 12 o'clock); this is commonly referred to as the cotton-swab test and constitutes the main diagnostic tool for vulvar vestibulitis; 5) the degree of vestibular erythema was evaluated by each gynecologist on a scale of 0 (none) to 3 (severe) and noted on a standardized form; 6) a unimanual and one digit single handed palpation was performed; 7) a standard bimanual palpation of the following areas was carried out: vagina (anterior vaginal wall, pubococcygeal muscle, uterosacral ligament), uterus (cervix and corpus with and without motion), and adnexae (with and without motion). Patients rated the pain at each site on a scale of 0 (no pain) to 10 (worst pain ever); a research assistant recorded patients' pain ratings on a standardized form for all of the above-mentioned sites. In addition, any other physical findings were noted, as were the gynecologists' final diagnoses. A structured interview and standardized questionnaires followed the gynecological examinations.

Participants were asked to remain untreated and to discontinue use of potential chemical allergens for a minimum of six weeks, at which point they were scheduled for two additional gynecological examinations, identical to the initial ones and carried out independently by the same gynecologists. The order of gynecologists carrying out the examination at time 1 was reversed at time 2. Based on the above procedure, we found substantial inter-rater reliability for the diagnosis of vulvar vestibulitis (kappa values ranging from .66 to .68, and percentage agreement ranging from 93.8 to 98.9%) and moderate test-retest reliability (kappa values ranging from .49 to .54, and percentage agreement ranging from 93.9 to 96.7%) (Bergeron et al., 1998).

At the second appointment, participants were informed as to whether they met the study selection criteria or not. Women not meeting these criteria (N = 58) were referred appropriately. Twenty-three women met our selection criteria but did not take part in the

study; they either 1) could not be reached at the time of randomization (N = 5), 2) were unable to commit to the study procedures (planning to move, etc.) (N = 9), 3) were unwilling to be randomized (N = 7), or 4) were relieved of some of their pain at the time of randomization (N = 2). These 23 women were not significantly different from the women who agreed to be randomized on any of the sociodemographic or pretreatment dependent measures. Participants having provided written consent were randomized to one of three treatment conditions: vestibulectomy, sEMG biofeedback, or GCBT. All treatments were free of charge to the participants, as were the materials required to practice the exercises.

Vestibulectomy. The vestibulectomy condition consisted of a minor day surgical procedure involving the excision of the vestibular area followed by vaginal advancement. Participants were randomly assigned to one of two gynecologists with similar experience in carrying out vestibulectomies. These were the same who conducted the gynecological examinations (S. K. and K. P.). All women undergoing the vestibulectomy met with the gynecologist they had been assigned to in order to receive detailed information about vulvar vestibulitis and the surgery, as well as to sign formal hospital papers (including a consent form) given to any patient undergoing surgery. They also had to undergo a presurgery physical checkup and blood tests. The vestibulectomy lasted about 30 minutes and was conducted under general anesthesia. After the vestibulectomy was performed, participants were given analgesics and were recommended to take sitz baths as needed. They had direct telephone access to their treating gynecologist in case of complications; none were reported. Participants returned to work on average three days following the surgery. Six weeks postsurgery, each woman met again with her assigned surgeon for an assessment of the healing in the vulvar vestibule and verbal instructions concerning how to gradually resume intercourse.

sEMG Biofeedback. Biofeedback training involved the insertion (by the woman herself) of a small single-user sEMG sensor (about one and a half inch long and one inch

wide) into the vagina. Insertion of the sensor took place in private. The participant was fully clothed during the biofeedback training sessions. An initial pelvic floor muscle sEMG assessment was conducted at session 1, which also involved education about vulvar vestibulitis and information about the biofeedback treatment. The remainder of the treatment involved practicing a series of muscular contraction/relaxation exercises with a view to increasing proprioception, maintaining stable contractions and using the pelvic floor muscles exclusively. The procedure for sEMG measurement of pelvic floor musculature is well worked out and reliable (Glazer et al, 1995; White, Jantos, & Glazer, 1997).

The two therapists to whom participants were randomly assigned were Ph.D. level clinical psychologists who received an intensive two-day training workshop and weekly telephone supervision by Howard I. Glazer, Ph.D. The two female therapists were similar in age and professional experience. They used the following automated protocol: 1) One 60-second prebaseline rest period; 2) Six maximum intensity rapid contractions or flicks (phasic contractions). Each contraction is preceded by a 12-second rest period; 3) Six maximum intensity 12-second contractions (tonic contractions). Each contraction is preceded by a 12-second rest period; 4) One maximum intensity 60-second contraction (endurance contraction) preceded by a 30-second rest; 5) One 60-second postbaseline rest period. During the remainder of the sessions, therapists focused on issues concerning treatment compliance, progress, difficulties with practice and negative or counterproductive practice habits. Sexual functioning was not discussed except at the initial assessment, which was co-led by Dr. Glazer himself. Weekly 45 minute-sEMG biofeedback training sessions were given to the patients for four weeks. These sessions were then given once every two weeks for a period of eight weeks, for a total of eight training sessions over a period of 12 weeks. This treatment also included training in the use of a portable sEMG home trainer for daily home practice sessions. Each home practice session consisted of 60 repetitions of a 10-second relaxation period alternated

with a 10-second maximum contraction period (20 minutes). Home practice sessions were prescribed twice a day. Instructions for home training were given both orally in the initial session and in writing on a handout.

The following instrumentation was employed: a) a surface electromyographic single-user vaginal sensor, b) a portable sEMG biofeedback instrument, and c) computerized electromyographic data acquisition equipment. The sEMG single-user vaginal sensor (Model T6050) is manufactured by Thought Technology Ltd., Montréal, Québec, Canada. This single-user sensor eliminates concerns about adequate sterilization, is easily inserted by the patient in private, with minimal instruction, minimal discomfort and without the need to completely disrobe.

The portable sEMG biofeedback instrument used by patients for home practice was specifically developed for use with the above described sensor for rehabilitation of pelvic floor musculature. It is a U-Control 60Hz Model T8825 manufactured by Thought Technology Ltd., Montréal, Québec, Canada. This instrument provides visual feedback in the form of a series of 15 lights. Microvolt range settings allow the biofeeback lights to be set to a range which matches the patient's contractile amplitudes. Two lights beside the biofeedback lights alternate illumination for 10 seconds each, instructing the patient to alternately contract and relax the pelvic floor muscles.

The computerized sEMG data acquisition system was used for assessments of pelvic floor musculature. It consisted of the FlexiPlus sEMG signal processing hardware and the Glazer Pelvic Floor Muscle Rehabilitation Program, Version 2.2 (Biobehavioral Medical Rehabilitation, Jacksonville, Florida) operating on a Pentium 166Hz laptop computer.

GCBT. GCBT involved a combination of cognitive and behavioral techniques aimed at reducing pain and improving sexual function. GCBT was delivered in a format of seven to eight women per group and consisted of two-hour sessions. The sessions were conducted once a week for four weeks by either one Masters (S. B.) or one Ph.D. level clinical psychologist specialized in cognitive-behavioral sex therapy. These sessions were

then given once every two weeks for a period of eight weeks. Participants were randomly assigned to either therapist taking into account the language of the group (French or English). The two female therapists were similar in professional experience and were trained before the study via a treatment manual designed specifically for this purpose by the first and second author of this paper. This training involved careful reading and discussion of the treatment manual before the beginning of the study as well as before each therapy session. Therapists also received joint weekly supervision with an experienced Ph.D. level cognitive-behavioral psychologist/sex therapist who was familiar with the manual. Adherence to the treatment manual was assessed by two trained clinical associates who viewed and coded a random sample of videotapes representing a quarter of all entire therapy sessions, with an inter-rater reliability of .87. Based on this coding of videotapes, therapists adhered to the treatment manual 89.6% of the time.

The treatment package included the following: information about the nature of GCBT; education and information about vulvar vestibulitis and how dyspareunia impacts on desire, arousal and orgasm; education concerning a multifactorial view of pain; education about sexual anatomy; relaxation techniques, Kegel exercises (contracting and releasing pubococcygeus muscles), vaginal dilatation exercises (inserting increasingly larger fingers into their vagina while in a relaxed state) and cognitive restructuring exercises (replacing erroneous or irrational beliefs about pain and sexuality by more realistic ones). Avoidance of sexual activities was also actively and regularly addressed.

Dependent Measures

The following outcome measures were administered at the first visit of the participant selection process (pretreatment), at posttreatment, and at 6-month follow-up. They involved, at each assessment, a structured interview, two independent gynecological examinations, and standardized questionnaires. Data for three of the pain measures

(vestibular pain index, Pain Rating Index and Sensory scale of the McGill Pain Questionnaire) were also collected at the second visit after the 6-week baseline period.

Pain. Pain dependent measures included: a) a vestibular pain index, derived from the two independent gynecological examinations conducted at each assessment. The participant pain ratings (scale of 0 to 10) taken during the cotton-swab test at six different points in the vulvar vestibule were averaged across the two gynecological examinations (per assessment) to form one single index of vestibular pain. Vestibular participant pain ratings have been found to correlate significantly between gynecologists for each palpation site, and the cotton-swab test has been shown to discriminate between women with and without vulvar vestibulitis (Bergeron et al., 1998); b) a self-report measure of the intensity of painful intercourse on a scale of 0 to 10, taken during the structured interview; c) the Pain Rating Index (PRI) of the McGill Pain Questionnaire (MPQ) (Melzack, 1975), a global score of the multidimensional pain experience, and d) the Sensory scale of the MPQ, comprised of adjectives that describe the sensory qualities of the pain. The rationale for including this scale rests on a finding from one of our previous studies, where 88.1% of vulvar vestibulitis participants chose adjectives referring to a thermal quality and 86.6% chose adjectives referring to an incisive pressure sensation, both being dimensions of the Sensory scale. (Bergeron et al., 1998). The MPQ is a well-known and widely used adjective checklist which assesses both qualitative and quantitative aspects of pain and is sensitive to the effects of different therapies on chronic pain (Melzack & Katz, 1992).

Sexual functioning. Sexual function dependent measures included: a) the Sexual History Form (Nowinski & LoPiccolo, 1979), a measure of sexual function evaluating desire, arousal, orgasm, frequency of sexual activities, and overall sexual satisfaction. Twelve of the original 28 items are used to calculate the Global Sexual Functioning score, which was used in this study and has demonstrated good reliability and validity (Creti et al., 1998). Lower scores indicate better sexual functioning; b) the Sexual Information

scale of the Derogatis Sexual Functioning Inventory (Derogatis & Melisaratos, 1979) is a reliable and valid measure of sexual knowledge which contains 26 true-false items; c) a self-report measure of frequency of intercourse per month, taken during the structured interview.

Psychological adjustment. Psychological adjustment was assessed using the Brief Symptom Inventory (Derogatis, 1992), a 53-item self-report inventory designed to reflect the psychological symptom patterns of psychiatric and medical patients as well as community non-patient respondents. It has 9 primary symptom dimensions and 3 global indices. We used the Global Severity Index, which is a measure of overall psychological distress.

Couple satisfaction. Relationship satisfaction was assessed using the Locke-Wallace Marital Adjustment Scale (Locke & Wallace, 1959), a brief 15 item measure of marital satisfaction that has become one of the standard measures of relationship satisfaction. It has undergone numerous reliability and validity studies supporting its ability to discriminate distressed from non-distressed couples. We adapted the scale to include cohabiting couples as well. Participants who were not cohabiting did not fill out this measure.

Participant evaluations. Two questions about treatment satisfaction [scale of 0 (completely dissatisfied) to 10 (completely satisfied)] and subjective improvement [scale of 0 (worse) to 5 (complete cure)] were incorporated into the posttreatment and 6-month follow-up interviews.

Adherence. Treatment adherence for sEMG biofeedback and sex therapy/pain management was measured via frequency ratings of weekly practice of exercises.

Credibility ratings. Treatment credibility was assessed at the first treatment session or during the presurgery appointment using two questions rated on a scale of 0 (not at all) to 10 (completely): 1) *Up to what point do you think the treatment you are receiving is*

logical in terms of its efficacy in alleviating vulvar vestibulitis syndrome? and 2) *How confident are you that the present treatment will improve your pain condition?*

Data Analytic Strategy

Data were analyzed using a repeated measures multivariate analysis of variance (MANOVA) approach with time as the within-subjects variable and treatment condition as the between-subjects variable. Outcome measures were clustered per conceptual domain (treatment credibility, pain, sexual function, patient treatment evaluations). When multivariate results were significant, univariate analyses were conducted. If significant, these were followed by planned contrasts or post-hoc comparisons with Bonferroni corrections. For variables not significantly correlated with any other (psychological adjustment, couple satisfaction), a repeated measures ANOVA approach was used. Greenhouse-Geisser adjustment was applied to compensate for violations of homogeneity of covariances. MANCOVA analyses on posttreatment and 6-month follow-up measures using pretreatment measures as covariates were also conducted. We report all the results of the MANOVAs because these analyses involve unadjusted means; results of the MANCOVAs are reported only when they are different from those of the MANOVAs. Percentage of pain reduction was computed for each treatment condition by substracting the 6-month follow-up mean from the pretreatment mean and dividing this value by the pretreatment mean. Correlational and chi-square analyses were used to investigate the relationship between sociodemographic variables and pretreatment dependent measures, as well as the relationship between socio-demographic variables, pretreatment dependent measures and treatment outcome on pain measures at 6-month follow-up in order to determine relevant covariates and to identify predictors of outcome.

Results

Final Sample Size

Nine women (seven from the vestibulectomy condition, one from the sEMG biofeedback condition, and one from the GCBT condition) who had agreed to participate dropped out of the study before receiving treatment. They were not different from the women who completed treatment on any of the sociodemographic or pretreatment dependent measures except for the Global Severity Index of the Brief Symptom Inventory ($t = -4.76$, $p < .0001$), on which they showed significantly more psychological distress. No further data were collected concerning these women. There were significantly more pretreatment drop-outs in the vestibulectomy condition, x^2 (2, $N = 87$) = 8.92, $p < .01$ than in the two other treatment conditions.

Two women from the sEMG biofeedback condition failed to attend the posttreatment assessment, and eight more dropped out before the 6-month follow-up. Three women from the vestibulectomy condition also failed to attend the 6-month follow-up assessment. There were significantly more drop-outs in the sEMG biofeedback condition, x^2 (2, $N = 78$) = 13.06, $p < .001$. The 13 drop-outs were not significantly different from the women who completed all three assessments on any of the sociodemographic or pretreatment dependent measures. They were included in the analyses by using imputations for missing values (carrying values forward) and reducing the error degrees of freedom by the number of estimated values in order to minimize the risk of Type I error. The final sample size thus included the 78 participants who underwent treatment. They were typically young, educated, nulliparous women with low income. This sociodemographic pattern is similar to that reported in other studies (e.g. Bazin et al., 1994; Foster, Robinson, & Davis, 1993). Detailed sociodemographic characteristics of the sample are shown in Table 1. There were no significant differences between treatment groups on any

of the sociodemographic variables or pretreatment dependent measures. In addition, none of the sociodemographic variables were significantly correlated with the pretreatment dependent measures.

Treatment Credibility

Treatment credibility ratings were high for all three groups, as shown in Table 2. Results from the MANOVA indicated a significant Treatment condition main effect, $F(4, 136) = 4.41$, $p < .002$. Univariate analyses demonstrated that GCBT participants' ratings were significantly lower than those of the vestibulectomy participants for logic of treatment, $F(2, 69) = 4.32$, $p < .02$, and for confidence in treatment, $F(2, 69) = 9.21$, $p < .0001$. Planned comparisons showed that GCBT participants' ratings were also significantly lower than those of the sEMG biofeedback participants for confidence in treatment, $F(2, 69) = 12.05$, $p < .001$. Correlational analyses with Bonferroni correction revealed that logic of treatment was inversely related to self-reported pain during intercourse at 6-month follow-up, $r = -.35$, $p < .01$. Treatment credibility ratings were not otherwise correlated with pain measures at 6-month follow-up.

Treatment adherence

Treatment adherence was defined as complying with at least 70% of the homework exercises. Sixty-five percent of GCBT participants complied with treatment, as compared to 57% of sEMG biofeedback participants. Chi-square analyses revealed no significant difference in adherence between treatment conditions. For the sEMG biofeedback and the GCBT groups analyzed separately or collapsed together, there were no significant correlations between degree of adherence to treatment regimen and 6-month follow-up measures of pain.

Pain Outcome Measures

There were no significant differences between the pretreatment measures and those taken immediately after the 6-week baseline period for the vestibular pain index (cotton-swab test), the PRI and the Sensory scale of the MPQ.

The means and standard deviations for the pain outcome measures by treatment condition and time of assessment are shown in Table 3. Results from the MANOVA indicated a significant Time main effect, $F(8, 68) = 18.44$, $p < .01$ and a significant Time X Treatment condition interaction, $F(16, 136) = 3.26$, $p < .01$. Univariate analyses indicated the following:

1) For the *vestibular pain index*, there was a significant Time main effect, $F(2, 74) = 53.68$, $p < .01$, a significant Treatment condition main effect, $F(2, 75) = 6.24$, $p < .01$, and a significant Time X Treatment condition interaction effect, $F(4, 148) = 13.24$, $p < .01$. Analysis of simple effects and planned comparisons revealed that at posttreatment, vestibulectomy participants had significantly lower pain levels on vestibular pressure than both GCBT participants, $F(2, 75) = 17.75$, $p < .01$, and sEMG biofeedback participants, $F(2, 75) = 20.60$, $p < .01$. The same pattern held true at the 6-month follow-up, $F(2, 75) = 7.72$, $p < .01$, and $F(2, 75) = 8.99$, $p < .01$. Participants from all three treatment conditions improved significantly from pretreatment to 6-month follow-up: vestibulectomy, $F(2, 74) = 59.66$, $p < .01$, sEMG biofeedback, $F(2, 74) = 6.59$, $p < .01$, and GCBT, $F(2, 74) = 10.26$, $p < .01$. Planned comparisons showed that both vestibulectomy, $F(2, 74) = 9.86$, $p < .01$ and sEMG biofeedback, $F(2, 74) = 99.95$, $p < .01$ participants significantly improved from pre- to posttreatment. The average percentage of pain reduction from pretreatment to 6-month follow-up was 70.0% for the vestibulectomy participants, 23.7% for the sEMG biofeedback participants, and 28.6% for the GCBT participants.

2) For the *self-reported pain intensity during intercourse*, there was a significant Time main effect, $F(2, 74) = 45.93$, $p < .01$, showing that taken together, participants significantly improved from pretreatment to 6-month follow-up. Post-hoc analyses revealed that participants as a whole significantly improved from pre- to posttreatment, $F(2, 74) = 45.45$, $p < .01$, and from posttreatment to 6-month follow-up, $F(2, 74) = 11.71$, $p < .01$. MANCOVA analyses using the pretreatment measure as a covariate yielded the following additional findings: a Treatment condition main effect was found, $F(2, 74) = 3.74$, $p < .05$, indicating that for posttreatment and 6-month follow-up taken together, participants from the vestibulectomy condition were significantly more improved than those from the GCBT condition. Planned comparisons indicated that participants from the vestibulectomy condition were also significantly more improved than those from the sEMG biofeeback condition, $F(2, 74) = 5.17$, $p < .01$. The average percentage of pain reduction from pretreatment to 6-month follow-up was 52.5% for the vestibulectomy participants, 35.0% for the sEMG biofeedback participants, and 37.5% for the GCBT participants.

3) For the *MPQ-PRI*, there was a significant Time main effect, $F(2, 74) = 12.22$, $p < .01$, showing that taken together, participants significantly improved from pretreatment to 6-month follow-up. Post-hoc analyses revealed that participants as a whole significantly improved from pre- to posttreatment, $F(2, 74) = 6.66$, $p < .01$, and from posttreatment to 6-month follow-up, $F(2, 74) = 11.09$, $p < .01$. The average percentage of pain reduction from pretreatment to 6-month follow-up was 46.8% for the vestibulectomy participants, 22.8% for the sEMG biofeedback participants, and 27.7% for the GCBT participants.

4) For the *Sensory scale of the MPQ*, there was a significant Time main effect, $F(2, 74) = 9.77$, $p < .01$, showing that taken together, participants significantly improved from pretreatment to 6-month follow-up. Post-hoc analyses demonstrated that participants as a whole significantly improved from pre- to posttreatment, $F(2, 74) = 6.17$, $p < .01$, and from posttreatment to 6-month follow-up, $F(2, 74) = 8.20$, $p < .01$. MANCOVA

analyses using the pretreatment measure as a covariate yielded the following additional findings: a Treatment condition main effect was found, $F(2, 74) = 3.79$, $p < .05$, indicating that for posttreatment and 6-month follow-up taken together, participants from the vestibulectomy condition were significantly more improved than those from the GCBT condition. Planned comparisons indicated that participants from the vestibulectomy condition were also significantly more improved than those from the sEMG biofeeback condition, $F(2, 74) = 4.23$, $p < .05$. The average percentage of pain reduction from pretreatment to 6-month follow-up was 47.1% for the vestibulectomy participants, 19.0% for the sEMG biofeedback participants, and 20.7% for the GCBT participants.

Sexual Function Outcome Measures

The means and standard deviations for the sexual function outcome measures by treatment condition and time of assessment are shown in Table 3. Results from the MANOVA indicated a Time main effect, $F(8, 68) = 4.00$, $p < .01$, but no interaction effect. Univariate analyses indicated the following:

1) For the *Sexual History Form*, there was a significant Time main effect, $F(2, 74) = 5.60$, $p < .01$, showing that as a whole, participants significantly improved from pretreatment to 6-month follow-up. Planned comparisons demonstrated that participants also significantly improved from posttreatment to 6-month follow-up, $F(2, 74) = 10.53$, $p < .01$. The mean for normal women aged 21-46 is .46 (Creti et al., 1998); at 6-month follow-up, participants from all three treatment groups are thus within the normal range.

2) For the *Information subscale of the DSFI*, there was a significant Time main effect, $F(2, 74) = 3.91$, $p < .05$, demonstrating that taken as a whole, participants significantly improved from pretreatment to 6-month follow-up. Planned comparisons revealed that participants were also significantly improved from pre- to posttreatment, $F(2, 74) = 4.63$,

$p < .05$. Means at all three assessment times are above the mean for female sexual dysfunction patients (20.22) and female non-patient normals (21.31) (Derogatis & Melisaratos, 1979).

3) For *frequency of intercourse*, there was a significant Time main effect, $F(2, 74) = 10.80$, $p < .01$, showing that taken together, participants significantly improved from posttreatment to 6-month follow-up. Planned comparisons did not demonstrate a significant difference between pretreatment and 6-month follow-up. Means at all three assessment times are below the mean frequency of intercourse for women aged 25-29, which is 7.5 times per month (Laumann et al., 1994).

Couple Satisfaction Outcome Measure

The means and standard deviations for the *Locke-Wallace Marital Adjustment Scale* by treatment condition and time of assessment are shown in Table 3. Results from the ANOVA yielded a significant Time X Treatment condition interaction, $F(4, 74) = 4.24$, $p < .01$. Analyses of simple effects revealed that for the GCBT condition, participants' couple satisfaction significantly declined from pretreatment to 6-month follow-up, $F(2, 37) = 8.00$, $p < .01$. Planned comparisons showed that their satisfaction also significantly declined from pre- to posttreatment, $F(2, 37) = 11.53$, $p < .01$. ANCOVA analyses using the pretreatment measure as a covariate yielded the following additional findings: a Treatment condition main effect was found, $F(2, 37) = 6.04$, $p < .01$, indicating that for posttreatment and 6-month follow-up taken together, participants from the vestibulectomy condition were significantly more satisfied with their relationship than those from the GCBT condition. Planned comparisons showed that sEMG biofeedback participants were also significantly more satisfied with their relationship than those from the GCBT condition, $F(2, 37) = 4.43$, $p < .05$. Means at all three assessment times are above or within norms (mean for women = 108.4) (Kimmel & Van der Veen, 1974).

Psychological Adjustment Outcome Measure

The means and standard deviations for the *BSI-GSI* by treatment condition and time of assessment are shown in Table 3. Results from the ANOVA indicated a Time main effect, $F(2, 74) = 7.29$, $p < .01$, demonstrating that participants as a whole had a significantly better psychological adjustment at 6-month follow-up as compared to pretreatment. Planned comparisons also revealed that participants displayed a significantly better psychological adjustment at post- as compared to pretreatment, $F(2, 74) = 6.72$, $p < .01$. Means at all three assessments are below the clinical cut-off point (T-score = 63); at 6-month follow-up, participants from all three treatment conditions are within norms (T-score = 50) (Derogatis & Melisaratos, 1983).

Participant Evaluations

The means and standard deviations for the participant evaluations by treatment condition and time of assessment are shown in Table 3. Results from the MANOVA indicated a significant Time X Treatment condition interaction, $F(4, 144) = 3.85$, $p < .01$. Univariate analyses indicated the following:

1) For *subjective improvement*, there was a significant Time main effect, $F(1, 73) = 4.96$, $p < .05$, showing that participants as a whole reported a significant improvement from posttreatment to 6-month follow-up.

2) For *treatment satisfaction*, there was a significant Time X Treatment condition interaction, $F(2, 73) = 4.55$, $p < .05$. Analyses of simple effects revealed that sEMG biofeedback participants were significantly less satisfied at 6-month follow-up as compared to posttreatment, $F(1, 73) = 6.57$, $p < .05$, and that sEMG biofeedback participants were significantly less satisfied than vestibulectomy participants at 6-month follow-up, $F(2, 73) = 4.18$, $p < .05$. Planned comparisons indicated that sEMG

biofeedback participants were also significantly less satisfied than GCBT participants at 6-month follow-up, $F(2, 73) = 4.17$, $p < .05$.

In order to further explore treatment satisfaction, we conducted correlational analyses (with Bonferroni correction) to find out whether satisfaction was associated with symptom reduction on our pain outcome measures. At 6-month follow-up, satisfaction was significantly inversely correlated with pain during the cotton-swab test (vestibular pain index), $r = -.61$, $p < .001$. The same pattern of results was found for self-reported pain intensity during intercourse, $r = -.57$, $p < .005$, and for the MPQ-PRI, $r = -.51$, $p < .01$.

Treatment success

Treatment success was defined as a self-reported great improvement or complete relief of pain on the subjective improvement measure of the participant treatment evaluations (4 or 5 on a scale of 0 to 5). For the vestibulectomy treatment condition, 63.6% of participants can be considered to have a successful outcome at posttreatment, and 68.2% at 6-month follow-up. However, 9.1% of participants (N = 2) were worse at posttreatment. These two participants' subjective impression was confirmed by all of their pain measures except the vestibular pain index. For the sEMG biofeedback condition, 30.8% can be said to have a successful outcome at posttreatment, and 34.6% at 6-month follow-up. For GCBT, 17.9% can be viewed as successful outcomes at posttreatment, and 39.3% at 6-month follow-up.

Predictors of treatment outcome

In order to examine the extent to which 6-month follow-up results on our four pain outcome measures were associated with pretreatment or sociodemographic variables, we

conducted a series of correlational analyses using a Bonferroni correction. No pretreatment or sociodemographic variables were significantly associated with the pain outcome variables, except for the previously reported negative correlation between logic of treatment and self-reported pain during intercourse at 6-month follow-up (Treatment credibility section).

Discussion

Four main conclusions can be drawn from the results of this study: 1) there are potentially efficacious biological and psychosocial treatments for vulvar vestibulitis; 2) based on pain measures, vestibulectomy is significantly more successful than sEMG biofeeback and GCBT; 3) the three treatments provide equally positive sexual function and psychological adjustment outcomes; 4) gains are maintained at 6-month follow-up for participants in all treatment conditions.

These findings cannot be easily accounted for by a placebo or attention effect: 1) the mean duration of the vulvar vestibulitis problem prior to study entry was close to five years and most women reported trying a number of different medical treatments before entering the study; 2) important differential treatment effects were found; 3) GCBT participants did not experience a significant change in their pain with the cotton-swab test (vestibular pain index) from pre- to posttreatment, even though this was the treatment condition in which the women received the most clinical attention; 4) there were no significant changes in pain during the 6-week baseline period, despite multiple gynecological examinations, an extensive psychosocial evaluation, and the expectation of entering a treatment study.

Findings of this study show that vestibulectomy participants had significantly lower levels of pain during the cotton-swab test (vestibular pain index) of the gynecological examination than participants from the GCBT and sEMG biofeedback conditions, both at

posttreatment and at 6-month follow-up, and that when these two assessments were taken together (MANCOVA analyses), they also had significantly lower levels of pain during intercourse and lower MPQ Sensory scores. The high success rate of this treatment is also demonstrated by participants' evaluations of treatment (68.2% reported a great improvement or a complete cure) and by the average percentages of pain reduction (from 46.8% to 70.0%, depending on the outcome measure). Although it is problematic to infer etiology from treatment outcome, the superiority of vestibulectomy over the two behavioral treatments is consistent with the involvement of peripheral mechanisms in the development and maintenance of vulvar vestibulitis. The successful outcome of vestibulectomy needs nonetheless to be considered within a larger perspective. Two out of our 22 surgery participants were worse after the intervention, and seven women who had initially been randomized to vestibulectomy refused to go ahead with the treatment. Had we been able to include this subset of participants in our analyses, the results might not have supported the superiority of vestibulectomy. The high pretreatment drop-out rate further suggests that a significant percentage of women are reticent to undergo such an invasive procedure.

Decreases in pain for participants in the sEMG biofeedback condition range from 22.8% to 35.0%, depending on the outcome measure, and 34.6% of participants can be considered to have a successful outcome at 6-month follow-up. These numbers are somewhat lower than those reported in the first published retrospective study of sEMG biofeedback (Glazer et al., 1995), where the reported success rate was 52%. This may be linked to the way the treatment was delivered in this study as opposed to the Glazer et al. (1995) study, in which participants were 1) thought to be 100% compliant with homework exercises, 2) suffering from various types of vulvar pain as opposed to only vulvar vestibulitis, 3) receiving other concomittant treatments, an 4) the two therapists delivering the treatment were less experienced than the therapist in the original Glazer et al. (1995) study.

The significantly higher drop-out rate in the sEMG biofeedback as compared to the two other treatments and the significantly lower satisfaction rate at the 6-month follow-up show that a substantial number of participants experienced difficulties in following through with this intervention. This appears to be independent of the outcome because participants in the GCBT did not drop-out and had similar outcomes. It is possible that the large time investment and the repetitive exercises may be responsible for this negative effect. These results highlight the importance of carefully assessing patient characteristics such as motivation before considering sEMG biofeedback as an appropriate treatment. In terms of treatment mechanisms, sEMG biofeedback affects behavioral factors by reducing both resting muscle tension and instability as well as involuntary contraction upon penetration by teaching participants to gain more control over their pelvic floor muscles. Considering that sustained muscle tension may diminish blood flow to adjacent areas, sEMG biofeedback may also be affecting sensory factors by allowing blood to circulate more freely in the vaginal area.

Decreases in pain for GCBT participants range from 27.7% to 37.5%, depending on the outcome measure, and 39.3% of participants can be considered to have a successful outcome at 6-month follow-up. Such a degree of improvement resulting from a cognitive-behavioral approach is quite encouraging in light of findings from a meta-analysis conducted by Flor, Fydrich, and Turk (1992), who found that the average reduction in pain intensity for multidisciplinary pain clinic patients across 65 studies was 37%. In addition, no participants dropped-out of GCBT once the treatment had begun. GCBT may reduce anxiety by giving participants more control over their pain and by changing the meaning of the situation for them, thereby affecting cognitive and emotional factors. The group aspect of the treatment may produce change in social expectations by normalizing dyspareunia for participants. GCBT appears to do little for the sensory component of pain, as shown by results of the cotton-swab test (vestibular pain index) and the Sensory scale of the MPQ. Similar to other psychological treatments, we notice that it took a

longer period of time for the GCBT participants to benefit from the positive effects of the therapy. This should be taken into consideration in clinical settings when dispensing cognitive-behavioral sex therapy and pain management. The significantly lower initial treatment credibility of GCBT may have affected outcome; the negative correlation between the logic of treatment and self-reported pain during intercourse at 6-month follow-up supports this hypothesis. Such findings highlights the need to improve our presentation of psychological pain treatments to patients. As Turk and Rudy (1990) have pointed out, programs involving psychological interventions often sound like 'learn to live with pain' kinds of treatments, a message that may be incompatible with patients' own goals and expectancies.

All three treatments have an equally positive effect on sexual functioning and psychological adjustment. GCBT appears to impact on relationship adjustment in a negative way; this may only reflect the disruption of the couples' status quo, since this treatment is the only one in which the partner is involved, by way of his participation in the homework exercises. The finding that women assigned to GCBT do not improve their sexual functioning significantly more than the others remains puzzling. This may be due to the fact that improved sexual function is dependent on the degree of pain that one experiences. However, the results also show that a significant reduction in pain, as found in the vestibulectomy condition, does not necessarily bring about increased frequency of intercourse or better overall sexual functioning. These conflicting results highlight the need for our research designs to take into account the multifactorial nature of dyspareunia by incorporating measures targeting behavioral, somatic, cognitive, affective, sexual, and relational dimensions of the pain, something that is rarely done in treatment outcome studies of vulvar vestibulitis (Bergeron et al., 1997). Furthermore, they suggest that multimodal treatment approaches may be essential to achieve significant improvement in all aspects of the disorder (Bergeron, Binik, Khalifé, Meana et al., 1997)

Indeed, medical and psychosocial treatments are not mutually exclusive and can be combined in an effort to provide women suffering from dyspareunia with the best possible outcomes. Within a multidisciplinary framework, GCBT and sEMG biofeedback represent promising alternatives to vestibulectomy because they do not involve significant physical risks. Future studies should consider combining behavioral interventions such as GCBT and sEMG biofeeback to evaluate whether their effects are additive and can equal those of vestibulectomy.

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Table 1

Sociodemographic characteristics of the sample

Variable	Vestibulectomy	sEMG Biofeedback	GCBT	Total
Age (years)				
M	26.2	27.0	27.1	26.8
SD	4.8	6.3	5.0	5.4
Pain duration (months)				
M	56.4	63.4	52.3	57.4
SD	35.9	65.2	41.0	49.5
Education (years)				
M	15.5	16.0	16.3	16.0
SD	3.3	2.0	1.8	2.4
Religion				
Catholic	14	16	17	47
Protestant	1	2	1	4
Jewish	1	0	2	3
Other	0	2	0	2
None	6	8	8	22
Place of birth				
North America	22	25	24	71
Europe	0	3	2	5
Latin/South Amer.	0	0	1	1
Other	0	0	1	1
Marital status				
No partner	5	4	5	14

Dating	5	8	6	19
Cohabiting	10	11	12	33
Married	2	5	5	12
Language of interview				
French	18	21	19	58
English	4	7	9	20
Annual income				
0 - 19 999$	8	11	15	34
20 000 - 39 999$	6	3	3	12
40 000 - 59 999$	4	8	4	16
> 60 000$	4	6	6	16
Ever experienced childbirth				
Yes	1	3	1	5
No	21	25	27	73

Note. GCBT = group cognitive-behavioral therapy; sEMG = surface electromyographic.

Table 2

Credibility ratings by treatment condition

Variable	Vestibulectomy	sEMG Biofeedback	GCBT
Logic			
M	8.31	8.14	7.32
SD	1.40	1.30	1.12
Confidence			
M	8.31	7.96	6.68
SD	1.49	1.35	1.36

Note. GCBT = group cognitive-behavioral therapy; sEMG = surface electromyographic.

Table 3

Dependent Measures by Time of Assessment and Treatment Condition

	Pretreatment		Posttreatment		6-month follow-up	
Measure and group	M	SD	M	SD	M	SD
Pain						
Vestibular pain index						
Vestibulectomy	6.34	1.85	1.89	1.68	1.90	2.24
sEMG Biofeedback	5.79	1.59	4.55	2.36	4.42	2.63
GCBT	5.45	1.88	5.26	2.00	3.89	2.09
Pain intensity during intercourse						
Vestibulectomy	7.18	1.62	3.93	3.25	3.41	3.17
sEMG Biofeedback	6.93	1.80	5.43	2.36	4.50	2.63
GCBT	7.14	1.53	6.00	2.13	4.46	2.47
MPQ-PRI						
Vestibulectomy	26.82	14.68	15.86	16.18	14.27	13.06
sEMG Biofeedback	26.46	15.99	23.79	17.23	20.43	18.10
GCBT	28.93	12.29	27.75	15.09	20.93	14.18

MPQ-Sensory scale						
Vestibulectomy	17.86	8.40	10.82	9.74	9.45	8.19
sEMG Biofeedback	17.07	8.34	15.57	10.18	13.82	10.66
GCBT	18.61	7.28	18.68	8.69	14.75	8.87
Sexual Function						
Sexual History Form						
Vestibulectomy	0.47	0.11	0.49	0.14	0.45	0.15
sEMG Biofeedback	0.51	0.11	0.51	0.08	0.48	0.08
GCBT	0.51	0.13	0.49	0.12	0.48	0.11
Frequency of intercourse						
Vestibulectomy	4.61	4.30	1.44	2.85	5.74	5.47
sEMG Biofeedback	3.38	2.91	3.43	3.04	4.04	4.56
GCBT	3.69	3.22	3.25	3.84	3.92	3.77
DSFI, Information subscale						
Vestibulectomy	21.68	1.91	22.41	1.74	22.46	1.90
sEMG Biofeedback	21.46	2.33	22.18	1.61	22.36	1.81
GCBT	21.82	2.31	21.75	2.15	22.25	1.84
Psychological Adjustment						
BSI-GSI						
Vestibulectomy	53.32	9.62	52.00	8.25	50.09	10.49

sEMG Biofeedback	54.11	8.78	51.29	8.93	50.79	9.39
GCBT	56.36	8.11	52.89	7.21	51.79	7.61
Couple Satisfaction						
L-W MAS						
Vestibulectomy	111.73	17.02	117.45	17.53	121.00	12.67
sEMG Biofeedback	116.31	13.79	117.13	14.09	111.56	17.72
GCBT	114.35	23.51	108.06	22.38	110.19	22.75
Participant evaluations						
Satisfaction						
Vestibulectomy	-		7.11	2.85	7.73	2.69
sEMG Biofeedback	-		6.54	2.55	5.62	3.03
GCBT	-		6.91	1.42	7.07	2.09
Improvement						
Vestibulectomy	-		3.27	1.49	3.32	1.46
sEMG Biofeedback	-		2.46	1.24	2.69	1.46
GCBT	-		2.43	1.07	3.00	1.09

Note. GCBT = group cognitive-behavioral therapy; sEMG = surface electromyographic; MPQ-PRI = McGill Pain Questionnaire - Pain Rating Index; DSFI = Derogatis Sexual Functioning Inventory; BSI-GSI = Brief Symptom Inventory - Global Severity Index; L-W MAS = Locke-Wallace Marital Adjustment Scale.

General Conclusion and Directions for Future Research

As this thesis is manuscript-based, the interpretation and implications of each set of results are highlighted in the appropriate section of each individual paper. Thus this conclusion section will focus primarily on directions for future research.

Overall, the review of the literature and the results of the three empirical studies support the view that vulvar vestibulitis is a pain syndrome that can be reliably diagnosed and successfully treated by interventions targeting sensory, cognitive and behavioral dimensions of the pain. However, the large percentage of women who chose adjectives from the Sensory scale of the McGill Pain Questionnaire (Melzack, 1975) as well as the success of vestibulectomy suggest that, contrary to what might have been expected in the case of a problem often conceptualized as a sexual dysfunction or a psychosomatic illness, cognitive, affective and behavioral aspects may play a less important role than what was traditionally believed.

The randomized treatment outcome study presented in this thesis had a 6-month follow-up, which is standard practice. With a view to testing the durability of the treatment effects we reported, a 2.5 year follow-up of our randomized treatment outcome study participants is planned for January 1999. The major dependent measures that were administered at the 6-month follow-up will be given again to the participants. These include measures of pain such as the cotton-swab test carried out during a gynecological examination as well as standardized questionnaires pertaining to sexual functioning, psychological adjustment and relationship satisfaction. We hypothesize that treatment gains will have remained the same or will have improved and that the frequency of intercourse will have increased. In addition, we are planning a multicenter randomized treatment outcome study that will combine cognitive-behavioral therapy and surface electromyographic biofeedback and compare this integrated behavioral treatment to vestibulectomy. Questions of interest include: 1) Is a combination of behavioral

treatments more successful than either one alone? 2) Is a combination of behavioral treatments as successful as vestibulectomy, both in terms of symptom reduction and of cost-effectiveness? 3) Which treatments work best for which biopsychosocial profiles? 4) Is success with cognitive-behavioral therapy associated with reductions in catastrophization and other cognitive distortions (Sullivan, Bishop, & Pivik, 1995)? 5) Do women with a positive sexual self-schema (Andersen & Cyranowski, 1994) benefit more from treatment, and is this true for all treatment modalities?

As another extension of the research presented in this thesis, we will soon begin to recruit matched controls in order to compare them to the women who took part in the selection process of our randomized treatment outcome study. Matched controls will undergo the same protocol that was administered pre-treatment to the vulvar vestibulitis participants. Aside from the measures mentioned in the report of the randomized treatment outcome study (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 1998), the protocol included extensive measures of somatization and sexual and physical abuse. This design will enable us to test hypotheses concerning, among other issues, the roles of anxiety, depression and somatization in sexual morbidity and the experience of pain, and whether women with vulvar vestibulitis have higher rates of sexual and physical abuse as well as of somatization. There are many unsubstantiated claims concerning the psychosexual functioning of vulvar vestibulitis sufferers, most of which have never been the subject of rigorous research. This study will clarify some of these misconceptions and will also provide a test of additional hypotheses which have never been examined in a large-scale controlled study, such as the co-occurence of vulvar vestibulitis and other unexplained pain problems (interstitial cystitis, fibromyalgia, etc.).

At the beginning of our randomized treatment outcome study, we asked our participants whether their male partners (when relevant) would be interested in taking

part in a related study. Forty-three partners filled out questionnaires pertaining to their couple satisfaction, psychological adjustment and sexual function, the same questionnaires that the women had filled out. The data will allow us to characterize the psychosexual profiles of the partners of women with vulvar vestibulitis as well as to compare them to normative data. Additionally, it might provide answers to questions concerning the relationship between couple satisfaction, psychological adjustment, and pain. Results from this study can contribute to design treatment programs tailored to the specific needs of dyspareunic women and their partners.

There are numerous other directions that research pertaining to vulvar vestibulitis could take, some of them less related to the content of this thesis. For example, one could focus on a more in-depth exploration of the role of the partner. Current findings in the health psychology literature suggest that significant others have an indirect impact on disease status via variables such as pain behaviors (Burman & Margolin, 1992). Several studies investigating other pain problems have confirmed that the spouse can contribute to reinforce and/or aggravate the pain (Flor, Kerns, & Turk, 1987; Flor, Turk, & Rudy, 1989; Lousberg, Schmidt, & Groenman, 1992). More specifically, these studies demonstrated that spouse solicitousness was associated with increased pain severity. One of the interesting aspects of dyspareunia is that the pain occurs within the context of an intimate activity - sex - in which the partner triggers and witnesses the woman's pain-related behaviors and emotional reactions. For this reason, it constitutes an ideal situation to explore key hypotheses relating to the role played by the partner in the experience of pain and can serve as a model for other types of pain syndromes.

Another crucial and neglected issue is that of measurement. A field of research can only take off and grow once there are valid and reliable measures that allow for a rigorous investigation of the phenomena at hand. Traditional pain measures are not always adequate to fully assess dyspareunia and its associated consequences. We have developed a diary-type measure of pain during intercourse and other activities; we plan

to validate this measure in an effort to circumvent the problem of retrospective data reporting.

There is also an important need to pursue human and animal research regarding the sensory components of the pain, for example by conducting sensory testing to examine tactile and pain thresholds in women with vulvar vestibulitis as compared to controls. Such a study is presently being carried out in our laboratory (Pukall, Binik, Abbott, & Khalifé, 1998). Although there have been excellent animal studies (e.g. Berkley, Benoist, Gautron, & Guilbaud, 1995), more research is needed to map out the neuroanatomy of the female reproductive system in humans in order to find out more about the basic mechanisms underlying genital and pelvic pain. To this end, future studies should aim at gaining a broader understanding of the structural and functional pathways which transmit information about painful sensations from the female reproductive system to the brain (Wesselmann, Burnett, & Heinberg, 1997).

Despite the fact that many pain problems appear to have menstrual variations (Berkley, in press), few systematic studies have been conducted regarding chronic pelvic and vulvar pain. There are anecdotal reports of an increase in pain intensity immediately preceding menses (e.g. Peckham, Maki, Patterson, & Hafez, 1986) and of changes in pain intensity depending on menstrual phase (Friedrich, 1987). In addition, one controlled investigation has shown that women who had first used oral contraceptives before the age of 17 had an 11-fold increase in relative risk of developing vulvar vestibulitis (Bazin et al., 1994). Early menarche was also associated with an increased risk. Another controlled study has recently demonstrated strong menstrual variations in the muscle pain thresholds of women suffering from dysmenorrhea (Giamberardino, Berkley, Iezzi, de Bigontina, & Vecchiet, 1997). More studies are needed to examine the relationship between menstrual cyclicity and the different types of dyspareunia and chronic pelvic pain. Questions to investigate might include: 1) which

aspects of the pain experience are affected by cyclicity (e.g., sensory, affective, evaluative, etc.)? and 2) does pain intensity vary depending on hormonal status?

In addition to the fact that these research questions have the potential to lead to crucial prevention measures and to novel treatment strategies, the adoption of a biopsychosocial framework in the study of dyspareunia will also likely inform us about issues common to other idiopathic pain problems.

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APPENDICES

Appendix 1 - Consent Form

The Surgical Treatment of

Vulvar Vestibulitis Syndrome: A Follow-up Study

Hôpital du Saint-Sacrement
Centre hospitalier affilié à l'Université Laval
1050, chemin Sainte-Foy, Québec, G1S 4L8

FORMULE DE CONSENTEMENT

PROJET DE RECHERCHE

Etude de suivi sur la vestibulectomie

Depuis quelques années, un nombre croissant de femmes sont référées aux gynécologues de l'Hôpital du Saint-Sacrement pour de la douleur ou de l'inconfort à la région de la vulve lors des relations sexuelles (dyspareunie superficielle). Cet inconfort, associé à une rougeur vulvaire localisée, fait partie d'un syndrome appelé "vestibulite vulvaire". Après investigation, le médecin propose des traitements à base de crèmes appliquées localement, d'injections au niveau de la vulve ou une intervention chirurgicale appelée vestibulectomie.

Le département d'obstétrique-gynécologie de l'Hôpital du Saint-Sacrement en collaboration avec le département de psychologie de l'Université McGill de Montréal réalise présentement une étude afin d'évaluer le résultat de l'intervention chirurgicale "vestibulectomie" sur l'évolution de la condition. Pour cette étude, nous avons besoin de la collaboration de femmes âgées entre 15 et 35 ans qui ont subi une vestibulectomie à l'Hôpital du Saint-Sacrement.

Si j'accepte de participer à cette étude, je devrai répondre à une entrevue téléphonique initiale axée sur mon histoire gynécologique, la vestibulectomie que j'ai subie, la douleur vulvaire, ma vie sexuelle et ma vie de couple. Cette entrevue téléphonique sera dirigée par Sophie Bergeron, étudiante au doctorat en psychologie sous la responsabilité du docteur Irv Binik, professeur au département de psychologie de l'Université McGill et directeur du service de thérapie sexuelle et de thérapie de couple de l'Hôpital Royal Victoria à Montréal. Ce questionnaire initial dure environ 10 minutes et pourra être suivi d'une entrevue plus élaborée à l'Hôpital du Saint-Sacrement sur le même sujet.

Si j'accepte cette entrevue plus élaborée, je devrai me rendre à la clinique externe de l'Hôpital du Saint-Sacrement pour rencontrer Sophie Bergeron. Je répondrai à un questionnaire extensif sur mes relations sexuelles, sur les résultats de la vestbulectomie et je quantifierai ma douleur sur une échelle visuelle. J'indiquerai mon accord ou non de participer à cette entrevue plus élaborée à la fin de l'entretien téléphonique initial. Je recevrai la somme de dix dollars (10.00$) à la suite de ma visite à l'Hôpital du Saint-Sacrement pour couvrir mes frais de transport ou de stationnement.

Je comprends que les renseignements qui seront recueillis seront confidentiels et ne serviront qu'à des analyses statistiques. Je comprends que les réponses au questionnaire que je fournirai ne feront pas partie de mon dossier des archives médicales.

Il est entendu qu'un refus de ma part n'affectera en rien la qualité des soins que je suis en droit de recevoir de mon médecin.

Je suis libre de refuser ou de me retirer de cette étude en tout temps sans justification et sans que ceci ne me cause préjudice quant à la qualité des soins que je suis en droit de recevoir dans le futur. Je conserve tous mes droits en signant ce consentement.

Je comprends que je puisse à tout moment communiquer avec un des responsables de l'étude ou leur collaboratrice si j'ai des questions à poser au sujet de l'étude ou de ma participation.

J'accepte donc volontairement et librement de participer à cette étude sur le suivi de la vestibulectomie.

Nom de la participante	Signature de la participante	Date

Nom du titulaire de l'autorité parentale si la participante est mineure (âgée de moins de 18 ans)	Signature du titulaire de l'autorité	Date

Nom de l'investigateur	Signature de l'investigateur	Date

RESPONSABLES:
Docteur Céline Bouchard, Hôpital du Saint-Sacrement, Québec, (418) 682-7511
Docteur Michel Fortier, Hôpital du Saint-Sacrement, Québec, (418) 682-7511
Docteur Irv Binik, Hôpital Royal Victoria, Montréal, (514) 398-6094

COLLABORATRICE:
Sophie Bergeron, Hôpital Royal Victoria, Montréal, (514) 398-5323

Appendix 2 - Structured Telephone Interview

The Surgical Treatment of

Vulvar Vestibulitis Syndrome: A Follow-up Study

numéro de la participante: _____ date de la 1ère communication: _____
date de l'entrevue: _____

ETUDE DE SUIVI SUR LA VESTIBULECTOMIE

Questionnaire téléphonique

Bonjour. Mon nom est Sophie Bergeron. Je travaille en collaboration avec les Dr. Céline Bouchard et Michel Fortier de l'Hôpital du Saint-Sacrement. Nous avons reçu votre formulaire de consentement concernant l'étude sur la vestibulectomie. Je vous appelle afin de procéder à l'entrevue téléphonique telle que mentionnée dans le formulaire de consentement. Cette entrevue dure environ quinze minutes et est entièrement confidentielle. Désirez-vous faire l'entrevue maintenant ou préférez-vous que je vous rappelle à un moment où vous serez plus disponible? Maintenant _____ Rendez-vous ultérieur (**inscrire date**)_____ Je vais donc vous poser quelques questions d'ordre plus général et nous passerons ensuite à la vestibulectomie ainsi qu'à la douleur vaginale.

À moins d'indication contraire, les choix de réponses ne sont pas énumérés à la participante. Ils servent seulement à faciliter la tâche de l'intervieweure.

A. INFORMATION SOCIO-DÉMOGRAPHIQUE

1. Date de naissance: ____/____/____
   jour mois année

2. Lieu de naissance: _____

3. Date de la chirurgie: ____/____
   mois année

4. Lequel des points suivants décrit le mieux votre statut civil actuel?

   a) célibataire non engagée dans une relation
   b) célibataire avec un partenaire régulier depuis _____ année(s)
   c) en union de fait depuis _____ année(s)
   d) mariée depuis _____ année(s)

5. Combien d'années d'études avez-vous complétées? _____

B. DOULEUR

1. Depuis votre chirurgie, ressentez-vous encore de la douleur lors de vos relations sexuelles avec pénétration?

   a) oui
   b) non
   c) je n'ai pas de relations sexuelles avec pénétration **(question 9)**
   d) je n'ai pas eu de partenaire depuis ma chirurgie **(question 10)**

Veuillez specifier:

_____

_____

2. Jusqu'à quel point votre douleur s'est-elle améliorée suite à la chirurgie?

   a) Amélioration complète **(question 10)**
   b) Grande amélioration
   c) Amélioration moyenne
   d) Peu d'amélioration
   e) Pas d'amélioration

3. Quelle est la fréquence à laquelle vous ressentez cette douleur?

   a) rarement (10 - 20 % des fois que j'ai des relations sexuelles)
   b) à l'occasion (20 - 30 % des fois que j'ai des relations sexuelles)
   c) souvent (30 - 50 % des fois que j'ai des relations sexuelles)
   d) très souvent (50 - 75 % des fois que j'ai des relations sexuelles)
   e) presque toujours (75 -99 % des fois que j'ai des relations sexuelles)
   f) toujours (100 % des fois que j'ai des relations sexuelles)

4. Depuis votre vestibulectomie, avez-vous ressenti de la douleur avec tous vos partenaires sexuels?

   a) oui
   b) non
   c) je n'ai eu qu'un partenaire sexuel

   Veuillez specifier:

   _____

   _____

   _____

5. À quel moment de la relation sexuelle la douleur apparaît-elle généralement?

   a) avant que le pénis ne touche au vagin
   b) lorsque le pénis commence à entrer dans le vagin
   c) lorsque le pénis est complètement entré dans le vagin et commence un mouvement de va–et–vient
   d) immédiatement après la relation sexuelle
   e) plus d'une demi–heure après la relation sexuelle

6. Une fois la douleur apparue, durant quelles étapes de la relation sexuelle la ressentez-vous?

   a) seulement durant l'entrée du pénis
   b) seulement durant le mouvement de va–et–vient du pénis
   c) seulement pour un peu de temps après la sortie du pénis
   d) durant l'entrée du pénis et après sa sortie
   e) durant l'entrée du pénis et durant le mouvement de va-et-vient
   f) durant le mouvement de va–et–vient du pénis et quelque temps après sa sortie
   g) avant l'entrée du pénis, durant son mouvement de va–et–vient et après sa sortie

Spécifier la durée de la douleur:

Durée: _____ secondes
_____ minutes
_____ heures
_____ jours

7. À quel endroit de la région génitale ressentez-vous habituellement la douleur?

a) à l'entrée du vagin
b) à l'intérieur du vagin
c) dans la région abdominale ou du bassin

8. Quelle est l'intensité de la douleur maintenant?

a) faible
b) inconfortable
c) forte
d) sévère
e) insupportable

9. Depuis votre vestibulectomie, jusqu'à quel point la douleur vous empêche-t-elle d'avoir des relations sexuelles avec pénétration?

a) pas du tout
b) un peu
c) assez
d) beaucoup
e) extrêmement

10. Depuis votre vestibulectomie, avez–vous régulièrement ressenti de la douleur dans la région génitale à d'autres moments que la pénétration? OUI NON **Enumérer les items non mentionnés par la participante.**

a) friction due à des vêtements serrés OUI NON
b) quand vous urinez OUI NON
c) à l'insertion d'un tampon OUI NON
d) durant la masturbation avec la main ou avec un objet OUI NON
e) lorsque votre partenaire vous stimule manuellement OUI NON
f) lorsque votre partenaire vous stimule oralement OUI NON
g) lorsque votre partenaire insère un ou plusieurs doigts dans votre vagin OUI NON
h) lors d'un examen gynécologique de routine OUI NON
i) je ressens de la douleur d'une façon permanente, dans toutes les situations et sans raison apparente OUI NON
j) autre. OUI NON

Veuillez préciser:

_____
_____
_____

11. Depuis combien de temps êtes-vous sans douleur?

a) moins de 6 mois
b) moins d'un an
c) entre 1 et 2 ans
d) entre 2 et 3 ans
e) 3 ans et plus

12. Combien de temps après la chirurgie avez-vous été capable d'avoir une relation sexuelle avec pénétration sans douleur?

a) moins de 2 mois
b) entre 2 et 4 mois
c) entre 4 et 6 mois
d) entre 6 et 8 mois
e) 8 mois et plus

13. Pensez-vous à d'autres façons dont votre douleur vaginale a changé depuis la vestibulectomie? Veuillez spécifier:

_____

_____

_____

14. Comment croyez-vous que le fait de ressentir de la douleur vaginale lors des relations sexuelles a affecté votre vie? **Enumérer les items non mentionnés par la participante.**

a) estime de soi
b) joie de vivre / bien-être
c) relations sexuelles
d) communication dans le couple
e) intention d'avoir des enfants
f) relations interpersonnelles
g) image corporelle
h) santé mentale (psychologique)
i) féminité

Veuillez spécifier:

_____

_____

_____

OU, pour les femmes ayant répondu b)*non* en 1:

15. Comment croyez-vous que le fait de ne plus ressentir de douleur vaginale lors des relations sexuelles a affecté votre vie? **Enumérer les items non mentionnés par la participante.**

a) estime de soi
b) joie de vivre / bien-être
c) relations sexuelles
d) communication dans le couple
e) intention d'avoir des enfants
f) relations interpersonnelles

g) image corporelle
h) santé mentale (psychologique)
i) féminité

Veuillez spécifier:

_____
_____
_____

16. Quel était votre degré de confiance en l'efficacité de la vestibulectomie **avant** d'en subir une?

a) très confiante
b) assez confiante
c) moyennement confiante
d) peu confiante
e) très sceptique

17. Si c'était à recommencer, choisiriez-vous à nouveau de subir une vestibulectomie?

OUI NON

Veuillez spécifier:

_____
_____

18. Attribuez-vous votre absence de douleur actuelle à la chirurgie? OUI ___ NON __

Veuillez spécifier:

_____
_____
_____

C. COUPLE

1. **Avant** votre vestibulectomie, quelle était votre satisfaction en ce qui concerne l'entente et l'harmonie dans votre couple?

a) très satisfaite
b) assez satisfaite
c) moyennement satisfaite
d) peu satisfaite
e) pas du tout satisfaite

2. Êtes-vous satisfaite du support que vous a procuré votre partenaire en ce qui concerne votre douleur et votre chirurgie?

a) très satisfaite
b) assez satisfaite
c) moyennement satisfaite
d) peu satisfaite
e) pas du tout satisfaite

D. SEXUALITÉ

1. **Avant** votre vestibulectomie, quelle était la fréquence à laquelle vous vous masturbiez? _____ fois par mois.

2. Et depuis votre vestibulectomie? _____ fois par mois

3. **Avant** votre vestibulectomie, quelle était la fréquence à laquelle votre partenaire vous stimulait manuellement? _____ fois par mois

4. Et depuis votre vestibulectomie? _____ fois par mois

5. **Avant** votre vestibulectomie, quelle était la fréquence à laquelle votre partenaire ous stimulait oralement? _____ fois par mois

6. Et depuis votre vestibulectomie? _____ fois par mois

7. Avant votre vestibulectomie, combien de fois par mois en moyenne aviez-vous des relations sexuelles avec pénétration? _____ fois par mois

8. Et depuis votre vestibulectomie? _____ fois par mois

E.TRAITEMENTS

1. Depuis votre vestibulectomie, avez–vous essayé d'améliorer la douleur à l'aide d'autres moyens? OUI NON **(l'intervieweure encercle les catégories dans lesquelles se situent les méthodes ayant été employées et nomme les catégories n'ayant pas été mentionnées)**

   a) quelques changements mineurs OUI NON

   (par exemple, porter des sous–vêtements de coton, utiliser un savon doux ou aucun savon, bains spéciaux, etc.)

   b) changements dans vos pratiques sexuelles OUI NON

   (changer de position pour les relations sexuelles, demander à votre partenaire d'aller plus lentement

   essayer d'augmenter l'excitation sexuelle, par exemple, prolonger les jeux préliminaires, porter des sous–vêtements sexy, regarder des films érotiques, ou changer de partenaire)

   c) utiliser différentes crèmes OUI NON

   (un lubrifiant pour vous–même ou pour votre partenaire (par exemple, K–Y, Crisco), une crème hydratante (par exemple, Prevex ou autre crème sans prescription), une crème avec corticostéroïdes prescrite par un médecin, une gelée anesthésique (qui "gèle" la exemple, crème Premarin), une crème antifongique, prendre des vitamines (vitamine E, par exemple)

   d) psychothérapie OUI NON

(psychothérapie individuelle, thérapie de couple, thérapie sexuelle, hypnose, exercices de relaxation)

e) médecine douce/alternative OUI NON

remèdes homéopathiques, produits naturels, herbes, alimentation/diète (par exemple, réduire l'oxalate de calcium, le sucre, etc.), physiothérapie/ostéopathie, acupuncture, massothérapie, etc.

f) autres traitements médicaux OUI NON

thérapie hormonale par voie orale (comprimés tels que Premarin/Provera), antibiotiques, etc.

g) autres. Veuillez spécifier:

---

2. Parmi les méthodes que vous avez mentionnées, certaines vous ont-elles aidées à soulager la douleur? OUI _____ NON_____. **Si non, l'intervieweure passe à la question suivante. Si oui**: Pouvez-vous me dire lesquelles? Je vais vous rappelez les types d'interventions que vous avez essayées et vous me direz, pour chacune d'elles, si elles vous ont aidé ou non. **(l'intervieweure se réfère à la liste ci-dessus et encercle OUI ou NON pour chacun des types de traitements que la femme a essayés)**

3. Quel est le nom du gynécologue qui a effectué votre vestibulectomie?

_____

4. Y a-t-il d'autres membres de votre famille qui ont souffert ou souffrent présentement de douleur pendant la pénétration? OUI ___ NON ___

Veuillez spécifier:

---

5. Y a-t-il autre chose à propos de la douleur, la chirurgie, le traitement, ou votre gynécologue dont vous aimeriez nous faire part? Avez-vous des questions?

_____

_____

_____

6. Les informations que vous m'avez fournie aujourd'hui sont très importantes et utiles pour notre recherche. Seriez-vous intéressée à participer à une entrevue personnelle portant sur la vestibulectomie, dans le même genre que celle que nous venons de faire? L'entrevue se déroulerait à Québec (Sainte-Foy?) et durerait environ une heure. Nous paierions vos frais de transport et de stationnement.

OUI _____ NON_____

Si non, l'intervieweure passe au point suivant.
Si oui: Cette entrevue va sans doute avoir lieu d'ici quelques mois. Je vous rappellerai en mai pour vous donner un rendez-vous.

Vous avez répondu à toutes les questions. Je vous remercie de votre collaboration. Vous nous avez rendu un grand service et surtout, vous rendez service aux femmes qui souffrent de ce problème. Je vous téléphonerez d'ici quelques mois afin de vous communiquer les résultats de l'étude. Au revoir.

Durée de l'entrevue: _____

Appendix 3 - Advertisements

Randomized Treatment Outcome Study

L'UNIVERSITÉ McGILL
ET
L'HÔPITAL ROYAL VICTORIA

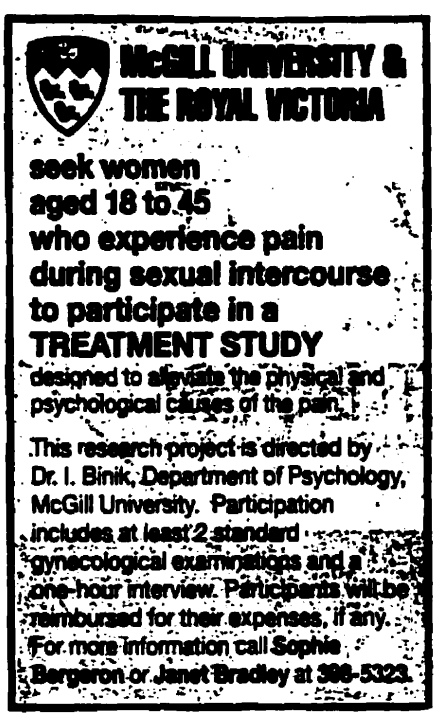
sont à la recherche de femmes âgées de 18 à 45 ans qui ressentent de la douleur lors des relations sexuelles afin de participer à une

ÉTUDES DE TRAITEMENT

des causes physiques et psychologiques de cette douleur. Ce projet de recherche est dirigé par le Dr I. Binik du Département de psychologie de l'Université McGill. La participation à ce projet comporte au moins 2 examens gynécologiques et une entrevue d'une heure. Les participantes seront remboursées pour leurs frais de déplacement s'il y a lieu. Pour plus d'information, communiquer avec:

Sophie Bergeron ou Janet Bradley au 398-5323

Le Journal de Montréal, January 27 1996



McGILL UNIVERSITY & THE ROYAL VICTORIA

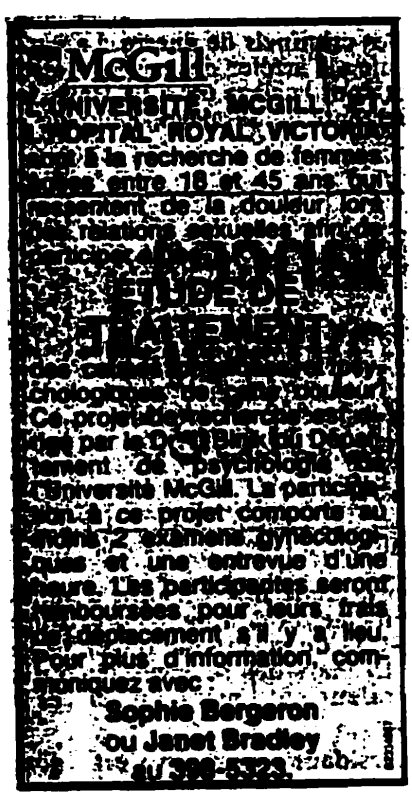
seek women aged 18 to 45 who experience pain during sexual intercourse to participate in a TREATMENT STUDY

designed to alleviate the physical and psychological causes of the pain.

This research project is directed by Dr. I. Binik, Department of Psychology, McGill University. Participation includes at least 2 standard gynecological examinations and a one-hour interview. Participants will be reimbursed for their expenses, if any.

For more information call Sophie Bergeron or Janet Bradley at 398-5323.

The Gazette
January 27 1996



McGill
UNIVERSITÉ McGILL ET
L'HÔPITAL ROYAL VICTORIA
sont à la recherche de femmes âgées entre 18 et 45 ans qui ressentent de la douleur lors des relations sexuelles afin de participer à une
ÉTUDE DE TRAITEMENT
des causes physiques et psychologiques de cette douleur. Ce projet de recherche est dirigé par le Dr I. Binik du Département de psychologie de l'Université McGill. La participation à ce projet comporte au moins 2 examens gynécologiques et une entrevue d'une heure. Les participantes seront remboursées pour leurs frais de déplacement s'il y a lieu. Pour plus d'information, communiquez avec
Sophie Bergeron
ou Janet Bradley
au 398-5323.

La Presse
January 27 1996

Pénétration douloureuse?

Près de 15 % des femmes souffrent de dyspareunie. C'est-à-dire qu'elles éprouvent des douleurs lors de la pénétration vaginale. Presque la moitié des cas seraient causés par le syndrome de la vestibulite vulvaire, une inflammation chronique du vestibule vulvaire — la région de la vulve où se trouvent les orifices du vagin et de l'urètre — , selon une étude menée en 1994 à l'université McGill, en collaboration avec l'hôpital Royal Victoria.

Même si les chercheurs ne connaissent pas encore la cause exacte de ce syndrome, plusieurs traitements prometteurs ont été élaborés: gestion de la douleur, biofeedback et ablation d'une petite partie du vestibule, à l'entrée du vagin. Cette chirurgie cause moins de dommages qu'un accouchement, selon le gynécologue Samir Khalifé. Une autre étude est présentement en cours, toujours à McGill et au Royal Victoria, et l'équipe est à la recherche de participantes. Les femmes choisies bénéficieront d'un traitement et d'un suivi gratuits. Pour faire partie de l'étude, communiquez avec Janet Bradley ou Sophie Bergeron au (514) 398-5323.

M.-F. C.

Magazine Santé, June 1996

Contre les relations douloureuses

Rougeurs à la vulve, douleur vive au début de la pénétration vaginale, sensation de brûlure? Diagnostic: vestibulite vulvaire. Ce syndrome affecte 5 % à 10 % des femmes, surtout dans la vingtaine et la trentaine. Il s'agit d'une inflammation chronique de la région de la vulve où se trouvent les orifices du vagin et de l'urètre. «La douleur est généralement très intense et localisée à l'entrée du vagin, mais certaines patientes n'éprouvent qu'une légère brûlure lors de la pénétration», précise le Dr Samir Khalifé, gynécologue à l'hôpital Royal Victoria. Si les causes ne sont pas encore connues, les hypothèses vont de divers allergènes aux infections (condylomes et candidose) en passant par les incontournables facteurs psychologiques. Dans un premier temps, les gynécologues conseillent à leurs patientes d'éliminer les allergènes potentiels: savons et produits de bain parfumés, dessous colorés (privilégier le coton blanc), serviettes sanitaires parfumées, tampons, lubrifiants, etc. Si la douleur persiste, on a recours à un gel anesthésique à base de lidocaïne appliqué à l'entrée du vagin, 5 à 10 minutes avant la relation. Au Royal Vic, en ce moment, on entreprend une étude de cas et on propose trois traitements: thérapie de gestion de la douleur, *biofeedback* pour apprendre à détendre les muscles autour du vagin (ils sont plus tendus chez celles qui souffrent de vestibulite vulvaire), ainsi que la vestibulectomie, qui consiste en l'ablation d'une petite partie du vestibule, à l'entrée du vagin. Pour participer à cette étude et obtenir traitement, soutien et suivi gratuits, on téléphone à Janet Bradley ou Sophie Bergeron, au (514) 398-5323.

MARIE-FRANCE CYR

Magazine Elle Québec, August 1996

Appendix 4 - Consent Forms

Randomized Treatment Outcome Study

Royal Victoria Hospital
Department of Obstetrics
and Gynecology
Department of Psychology
Montreal General Hospital
Department of Obstetrics and Gynecology
McGill University
Department of Psychology

A randomized controlled treatment outcome study for vulvar vestibulitis syndrome

Principal investigators
Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard I. Glazer,
Ms Sophie Bergeron and Mrs. Janet Bradley

SUBJECT CONSENT FORM #1

Purpose of the assessment

The purpose of this assessment is to find out if women interested in participating in a treatment study for vulvar vestibulitis syndrome, a type of intercourse pain, meet the selection criteria. The study to be conducted will investigate the effectiveness of three treatments for vulvar vestibulitis syndrome: vestibulectomy (a minor surgery), pain management and biofeedback. It will also investigate factors that are associated with treatment success. This attempt to better understand painful intercourse will help health professionals formulate more efficient treatments for women who experience this frustrating and disruptive condition.

Assessment procedures

The participant will take part in a structured interview and answer questionnaires which ask about her medical history, coital pain, sexuality, sexual attitudes, sexual abuse, relationships, and current physical and psychological symptoms (duration = 90 min.) and in 2 standard gynecological examinations which may include vaginal, cervical and urine cultures when indicated. These cultures consist of the gynecologist taking a smear from the cervix and another one from the vagina with a Q-tip. This procedure is painless and will only take a few seconds (like a Pap smear). Urine cultures are taken via a sample of urine, and thus involve urination (in private) in a small container.

Two separate gynecological examinations will be carried out by two different gynecologists-one by Dr. Khalifé and one by Dr. Pagidas. Typically, these exams will be carried out on one occasion. If the participant prefers, she will have the option of undergoing the second exam on another day. The goal of the second examination is to confirm the conclusions of the first. A female research assistant will be present during the examinations to write down the pain ratings that the participant will be asked to give at different points during the examinations. If after the exams the participant is still interested in participating in the study, she will be instructed to discontinue all types of treatments and use of potential allergens for a period of 6 weeks, at which time she will be reassessed (gynecological exams only). This procedure has 2 goals: 1) to ensure that the participant's vulvar pain is not simply caused by an allergen such as perfumed soap or a local cream, and 2) to ensure that the results of the study will indeed be due to the treatment administered during the 12-week period rather than to some other treatments used before entering the study. Moreover, the participant will be asked to fill out daily copies of the Daily Pain Monitoring Form for 2 periods of 2 weeks during the 6-weeks pre-treatment period. This will take 2 to 3 minutes a day.

The participant will be contacted by telephone within 2-3 weeks of the assessment and will be informed about the results of the testing. Any infection identified by the testing will be fully treated. The participant will be told if she meets the selection criteria for the study at the second assessment following the 6-week period. If she meets the selection criteria and is still interested in participating in the study, the entire process of the study will be explained to her in details. If she does not meet the selection criteria or if she is not interested in participating in the study, she will be given treatment suggestions and will be referred for appropriate treatment.

Benefits and risks

Participants taking part in this assessment will benefit from a complete evaluation of their vulvar pain by a multidisciplinary team of researchers and clinicians specialized in painful intercourse (dyspareunia) and will be given treatment recommendations, whether or not they participate in the treatment study. There are no risks involved in this assessment.

Compensation

The transportation costs of participants will be reimbursed to a maximum of 50$ for the entire treatment study on presentation of receipts.

Confidentiality

Two different records of the participant's examinations will be kept. The official hospital records will have her name on them and will be kept as are all hospital records. These will contain information about the gynecological exams only (and cultures if applicable). A second copy of results which will only be available to members of the research team will contain the assessment interview and questionnaires as well as the gynecological examinations. This second copy will only have a number on it.

Participant rights

Participation in this screening assessment procedure is completely voluntary and a refusal to participate will involve no penalty or loss of benefits. Furthermore, the participant is free to withdraw from this assessment at any time or to refuse to answer any questions posed without need of an explanation on her part. Finally, undergoing this assessment does in no way obligate her to participate in the treatment study. She can receive adequate treatment without participating in the study.

In the event that the participant has any complaints or dissatisfactions with this research, she can communicate them to one of the principal investigators or to Dr. Dennis Kalogeropoulos, Associate Director, Sex and Couple Therapy Service, Royal Victoria Hospital (tel. 842-1231, ext. 4284).

If the participant has any questions regarding her rights as a research subject, she may contact the Patient Representative at 842-1231, ext. 5655.

The screening assessment procedure for the study has been explained to me and my questions have been answered to my satisfaction. I agree to participate in the assessment procedure for the study entitled "A randomized controlled treatment outcome study for vulvar vestibulitis syndrome" conducted by Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard Glazer, Ms Sophie Bergeron and Mrs. Janet Bradley, as the principal investigators, Dept. of Obstetrics and Gynecology, and Sex & Couple Therapy Service, Royal Victoria Hospital and Department of Psychology, McGill University (398-6094).

I will be given a copy of this consent form for my records and future reference.

Signature _____

Name (print) _____

Date _____

Witness _____

Dr. Irv Binik _____

Hôpital Royal Victoria
Département d'Obstétrique
et de Gynécologie
Départment de Psychologie
Hôpital Général de Montréal
Département d'Obstétrique
et de Gynécologie
Université McGill
Départment de Psychologie

Une étude prospective de traitement du syndrome de la vestibulite vulvaire

Chercheurs principaux
Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard I. Glazer,
Mme Sophie Bergeron et Mme Janet Bradley

FORMULAIRE DE CONSENTEMENT #1

Objectif de l'évaluation

La présente évaluation a pour but de déterminer si les femmes intéressées à participer à une étude de traitement portant sur le syndrome de la vestibulite vulvaire (douleur pendant les relations sexuelles) rencontrent les critères de sélection. L' objectif de l'étude est d'examiner l'efficacité de trois modalités de traitement: a) la vestibulectomie (chirurgie), b) la thérapie sexuelle/gestion de la douleur, et c) la rétroaction biologique, ainsi que les facteurs associés à un résultat post-opératoire positif. Cette démarche vers une meilleure compréhension de la douleur vulvaire vise à aider les professionnels de la santé à développer des traitements plus efficaces pour les femmes comme moi qui souffrent de ce problème frustrant et dérangeant.

Procédures

La participante prendra part à une entrevue dirigée et répondra à des questionnaires portant sur son histoire médicale, sa douleur pendant les relations sexuelles, sa sexualité, ses attitudes sexuelles, l'abus sexuel, sa relation de couple et ses symptômes actuels, physiques et psychologiques (durée totale = 90 minutes). De plus, elle subira deux examens gynécologiques de routine qui pourraient inclure des cultures vaginales, cervicales et une culture d'urine, si indiqué. Dans ce cas, le gynécologue prendrait un prélèvement du

col de l'utérus et un autre du vagin, et ceci avec un Q-tip. Cette procédure ne durera que quelques secondes et ne causera aucune douleur (semblable à un Pap test). La culture d'urine nécessite la production d'un échantillon d'urine en privé.

Les deux examens seront faits par deux gynécologues-Dr. Khalifé et Dr. Pagidas, préférablement le même jour, quoique la participante est libre de choisir de subir le second examen à une date ultérieure. Le second examen a pour but de confirmer les conclusions du premier. Une assistante de recherche sera présente lors des examens afin de noter les évaluations de la douleur qu'on demandera à la participante de donner à différents moments des examens. Si, après les examens, la participante est toujours intéressée à prendre part à l'étude, on lui demandera de cesser tout traitement et toute utilisation d'allergènes potentiels pour une période minimale de six semaines, après quoi elle sera réexaminée afin de confirmer le diagnostic. Cette procédure a deux objectifs: 1) s'assurer que sa douleur n'est pas causée par un allergène (ex.: savon parfumé, crème vaginale, etc.), et 2) s'assurer que les résultats de l'étude ne seront dûs qu'au traitement qu'elle aura reçu et non à d'autres soins utilisés avant sa participation à l'étude. De plus, on lui demandera de noter sa douleur quotidiennement sur une feuille d'auto-observation pendant deux périodes de deux semaines. Ceci ne prendra que quelques minutes par jour.

Les résultats des tests seront communiqués à la participante par téléphone deux à trois semaines suivant les examens. Toute infection décelée lors des tests sera traitée.La participante saura si elle rencontre les critères de sélection de l'étude lors des examens suivant la période de 6 semaines. Si elle rencontre les critères de sélection et qu'elle est toujours intéressée à prendre part à l'étude, on lui expliquera le déroulement complet de l'étude. Si elle ne rencontre pas les critères de sélection, ou si elle n'est plus intéressée à participer à l'étude, on lui suggérera d'autres traitements et on la référera au professionel de la santé approprié.

<u>Risques et bénéfices</u>

Les participantes prenant part à cette évaluation bénéficieront d'une évaluation complète de leur douleur vulvaire par une équipe multidisciplinaire de chercheurs et de cliniciens spécialisés dans le traitement de la dyspareunie (douleur pendant les relations sexuelles). Elles recevront des recommendations de traitement, qu'elles participent dans l'étude de traitement ou non. Cette évaluation ne comporte aucun risque.

Compensation

Les coûts de transport des participantes seront remboursés jusqu'à concurrence de 50$ et ce pour toute l'étude de traitement, sur présentation de reçus.

Confidentialité

Les résultats de la présente évaluation seront inscrits dans deux dossiers: le premier, qui incluera les cultures et les résultats des examens gynécologiques, demeurera à l'hôpital et sera identifié par le nom de la participante. Le second dossier, qui incluera l'entrevue dirigée, les questionnaires ainsi que les résultats des examens gynécologiques, demeurera à la disposition de l'équipe de recherche seulement et sera identifié uniquement par un numéro.

Droits des participantes

Il est entendu que la participante n'est nullement obligée de prendre part à cette procédure de sélection et que son traitement ne sera affecté ni par son refus ni par son consentement. De plus, elle demeure libre de se retirer de cette évaluation en tout temps ou de refuser de répondre à n'importe quelle question, et ce, sans avoir à fournir d'explication. Finalement, sa participation à cette évaluation ne l'oblige pas à participer à l'étude de traitement. Elle peut recevoir un traitement approprié sans prendre part à l'étude.

Advenant que j'aie des plaintes ou des insatisfactions par rapport à cette recherche, je sais que je peux les communiquer à un des chercheurs principaux ou à Dr. Dennis Kalogeropoulos, Directeur Associé du Service de thérapie sexuelle et de thérapie de couple de l'Hôpital Royal Victoria (tél.: 842-1231, poste 4284).

Si j'ai des questions concernant mes droits comme sujet de recherche, je peux m'adresser au Représentant des Patients au 842-1231, poste 5655.

Les procédures d'évaluation m'ont été expliquées clairement et on a répondu à mes questions de façon satisfaisante. J'accepte de participer à cette procédure de sélection pour le projet de recherche intitulé "Une étude prospective de traitement du syndrome de la vestibulite vulvaire ", projet entrepris par Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard Glazer, Mme Sophie Bergeron et Mme Janet Bradley, principaux chercheurs, ainsi que le Département d'Obstétrique et de Gynécologie et le Service de thérapie sexuelle et de thérapie de couple de l'Hôpital Royal Victoria, de même que le Département de Psychologie de l'Université McGill (398-6094).

Une copie de ce formulaire de consentement me sera remis pour mes dossiers personnels et pour référence future.

Signature _____

Nom (lettres moulées) _____

Date _____

Témoin _____

Dr. Irv Binik _____

Royal Victoria Hospital
Department of Obstetrics
and Gynecology
Department of Psychology
Montreal General Hospital
Department of Obstetrics and Gynecology
McGill University
Department of Psychology

A randomized controlled treatment outcome study for vulvar vestibulitis syndrome

Principal investigators
Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard Glazer,
Ms Sophie Bergeron and Mrs. Janet Bradley

SUBJECT CONSENT FORM #2

Purpose of the study

This study is being conducted to investigate the relative effectiveness of three different treatments for vulvar vestibulitis syndrome (painful intercourse): 1) vestibulectomy (a minor surgery), 2) pain management, and 3) biofeedback. It will also investigate factors that are associated with treatment success. This attempt to better understand painful intercourse will help health professionals formulate more efficient treatments for women who experience this frustrating and disruptive condition.

Study procedures

The participant will be randomly assigned to one of the following treatment conditions: 1) vestibulectomy, 2) group pain management, or 3) biofeedback. This means that she will have no choice over which treatment she receives, which will be determined by chance. All treatments included in this study are standard treatments for vulvar vestibulitis syndrome.

Vestibulectomy A vestibulectomy is a minor day surgical procedure in which the painful vulvar area is removed and vaginal tissue is pulled down to cover this area. This procedure causes less damage to the vulvar area than giving birth. Vestibulectomy is the most common treatment for vulvar vestibulitis syndrome. Previous studies show that 60 to 85% of the women who undergo the surgery benefit from a significant improvement or complete

relief of their pain. This treatment condition also requires a visit to the pre-admission clinic for a physical checkup to assess the participant's general medical well-being and to undergo some blood tests. The total amount of blood taken will be about 30 ml (6 teaspoons). These blood tests are standard ones and include a CBC (complete blood culture) similar to the one the participant might have during a regular physical checkup with her family doctor, the measurement of serum electrolytes, and a determination of her blood group. Possible discomforts from blood tests include bruising and infection, although these are uncommon. This pre-admission clinic procedure is the same for all patients undergoing anesthesia at the Royal Victoria Hospital. The surgery itself lasts about 45 minutes and will be conducted under general anesthesia by Dr. Khalifé or Dr. Pagidas. There are certain risks to undergoing this surgical procedure. There is a rare chance that I might experience excessive bleeding, infections, hematoma (an effusion of blood into the vulvar tissue), a urethrovaginal fistula (an abnormal opening between the urethra and the vagina) or a rectovaginal fistula (an abnormal opening between the rectum and vagina). The risk of developing any of these complications is less than 1%. If the participant experiences a complication, she will contact her surgeon who will immediately treat the complication. There is a safe medical and/or surgical treatment for all possible complications. The participant can consult Dr. Khalifé or Dr. Pagidas to obtain more information about treatments for the above mentioned rare complications. There are also certain risks to the use of anesthesia. General anesthesia is sometimes followed by a brief period of nausea. Serious problems are extremely rare and are usually caused by oxygen deprivation. The risks of dying as a result of anesthesia, whatever the type, are extremely rare, approximately 1 in 200,000. No such death has occurred at the Royal Victoria Hospital in the past 25 years. After the surgery, the participant will be given general post-surgery instructions as well as instructions on how to facilitate healing of the area. She will be able to leave the hospital 2-3 hours after completion of the surgical procedure. She should ask someone to accompany or drive her home since there may still be some minor effects of anesthesia such as fatigue or slowed reaction time. These effects, if they occur, should be totally gone 5-6 hours after the surgery is completed. The participant might experience some vulvar pain during the week following the surgery, although this will not necessarily occur. If she experiences pain at this time, it will not last more than about a week. In any case, she will be given analgesics (pain killers) after the surgery, the cost of which will be paid by the researchers. Complete healing of the area will take from 8 to 12 weeks. The participant will be able to resume intercourse 12 weeks after the surgery. She will be able to return to work two days after the surgery.

Biofeedback The goal of biofeedback treatment is to train women experiencing painful intercourse to gain more control over their overly tensed pelvic floor muscles, which are thought to contribute to and maintain the pain. A previous study shows that 52% of women who undergo biofeedback training benefit from a complete relief of their pain and the average pain decrease for all women undergoing this treatment is 83%. Biofeedback training involves the insertion (by the woman herself) of a small single-user EMG sensor (about 1 1/2 inch long and 1 inch wide) into the vagina. Insertion of the sensor takes place in a private washroom of the examining room. The participant will be fully clothed during the biofeedback training sessions. An initial pelvic floor muscle EMG assessment will be conducted. The remainder of the treatment involves practicing series of muscular contraction/relaxation exercises, adapting the contractions to the feedback of the therapist and screen monitor, which are based on the measurement of pelvic floor muscle tension. The person carrying out the biofeedback training will be a Masters or Ph.D. level clinical psychologist. Weekly 1-hour biofeedback training sessions will be given for 4 weeks. These sessions will then be given once every 2 weeks for a period of 8 weeks, for a total of 8 training sessions over a period of 12 weeks. All training sessions will be carried out at the Royal Victoria Hospital. This treatment also includes training in the use of a portable EMG home trainer for daily home practice sessions (two 20-minute sessions per day of practice, 6 days/week, for a total of 4 hours/week of practice). The researchers will cover the cost of the portable EMG home trainer. Biofeedback treatment will not cause the participant to experience any more pain than usual.

Pain management The pain management treatment condition involves a combination of sex therapy and pain management techniques. Pain management techniques have traditionally been used to help patients cope with and reduce their pain (e.g. cancer pain, migraine headaches, etc.). Sex therapy techniques have been used to reduce the anxiety and lack of arousal associated with painful intercourse. It is assumed that these techniques also affect some physical components such as the relaxation of the vaginal muscles. Previous studies show that 43 to 68% of women who undergo sex therapy treatments benefit from a significant improvement or complete relief of their pain. Pain management treatment will be given in a group format (7-8 women per group) and will consist of 2-hour group sessions. The sessions will be conducted once a week for 4 weeks by a Masters or Ph.D. level clinical psychologist. These sessions will then be given once every 2 weeks for a period of 8 weeks. All sessions will be carried out at the Royal Victoria Hospital. The treatment package will include the following: education and information about pain and sexuality, education about sexual anatomy, relaxation techniques, Kegel exercises, vaginal dilatation

exercises and cognitive restructuring (replacing erroneous or irrational beliefs about pain and sexuality by more realistic ones). Use of these techniques involves weekly homework assignments (1 hour a week). Group pain management will not cause the participant to experience anymore pain than usual. At no time will the participant be in the obligation to discuss anything involving information about herself which she does not want to reveal.

Videotaping

Some sessions of the biofeedback and pain management treatment conditions will be videotaped for the purposes of the study. The videotaping will not require any cameraman; the video camera will be on a tripod. Access to these videos will be strictly reserved to members of the research team. They will be kept in a locked filing cabinet for 3 years after the end of the study, at which time they will be erased. Back ups will be kept in another locked filing cabinet and will also be erased 3 years after the end of the study. The participant will have to sign a Royal Victoria Hospital Audio-Visual consent form with regard to this videotaping.

Assessment procedures

The participant will undergo 2 more assessments as part of this study, both similar to the first one she underwent, although of a shorter duration. These will take place after 12 weeks of treatment (end of treatment), and 6 months after the end of treatment. Each assessment will involve a structured interview and questionnaires which ask about the participant's coital pain, sexuality, sexual attitudes, relationship(s), and current physical and psychological symptoms (duration = 60 min.), and 2 standard gynecological examinations which may include vaginal, cervical and urine cultures when indicated. These cultures consist of the gynecologist taking a smear from the cervix and another one from the vagina with a Q-tip. This procedure is painless and will only take a few seconds (like a Pap smear). Urine cultures are taken via a sample of urine, and thus involve urination (in private) in a small container.

The participant will be asked to fill out daily copies of the Daily Pain Monitoring Form on which she will keep a record of her pain 2 weeks per month during the treatment, and also two weeks per month during the 6 months follow-up period (prior to the final assessment of her pain).

The participant will be asked to discontinue all other types of treatments for the total duration of the study, which will last 9 months: 3 months of treatment and 6 months of

follow-up after which she will take part in the final assessment of her pain. The goal of this procedure is to ensure that the results of the study will indeed be due to the treatment administered during the 12-week period rather than to some other treatments that she might have used during my 9-month participation in the study.

Benefits and risks

Participants taking part in this study will benefit from one of three cutting-edge treatments and from regular evaluations of their vulvar pain by a multidisciplinary team of researchers and clinicians specialized in painful intercourse (dyspareunia). Other women currently suffering from this problem as well as future generations of women may also greatly benefit from the participant's involvement. No risks are involved in undergoing the biofeedback and pain management treatments. Rare risks involved in undergoing the vestibulectomy are underlined in the section on the description of this treatment modality.

Withdrawal from the study

The participant can withdraw from the study at any time by phoning Sophie Bergeron or Janet Bradley at 398-5323.

Alternative treatments

If the treatment of the participant's pain does not provide satisfactory results, she will be offered other treatment options through the usual hospital services. These options consist of the 2 other treatments studied in this project, as no other successful treatments exist in Montreal at this time.

Compensation

The transportation costs of participants will be reimbursed to a maximum of 50$ for the entire treatment study on presentation of receipts.

Confidentiality

Two different records of the participant's examinations will be kept. The official hospital records will have her name on them and will be kept as are all hospital records. These will contain information about the gynecological exams only (and cultures if applicable). A second copy of results which will only be available to members of the research team will contain the interviews and questionnaires as well as the gynecological examinations. This second copy will only have a number on it.

Participant rights

Participation in this treatment study is completely voluntary and a refusal to participate will involve no penalty or loss of benefits. Furthermore, the participant is free to withdraw from this study at any time or to refuse to answer any questions posed without need of an explanation on her part. She can receive adequate treatment without participating in the study, through regular hospital services.

In the event that the participant has any complaints or dissatisfactions with this research, she can communicate them to one of the principal investigators or to Dr. Dennis Kalogeropoulos, Associate Director, Sex and Couple Therapy Service, Royal Victoria Hospital (tel. 842-1231, local 4284).

If the participant has any questions regarding her rights as a research subject, she may contact the Patient Representative at 842-1231, ext. 5655.

The study has been explained to me and my questions have been answered to my satisfaction. I agree to participate in the study entitled "A randomized controlled treatment outcome study for vulvar vestibulitis syndrome" conducted by Dr. Irv Binik, Dr. Samir Khalife, Dr. Kelly Pagidas, Dr. Howard Glazer, Ms Sophie Bergeron and Mrs. Janet Bradley, as the principal investigators, Dept. of Obstetrics and Gynecology, and Sex & Couple Therapy Service, Royal Victoria Hospital and Department of Psychology, McGill University (398-6094).

I will be given a copy of this consent form for my records and future reference.

Signature _____

Name (print) _____

Date _____

Witness _____

Dr. Irv Binik _____

Hôpital Royal Victoria
Département d'Obstétriques et de Gynécologie
Départment de Psychologie
Hôpital Général de Montréal
Département d'Obstétriques et de Gynécologie
Université McGill
Départment de Psychologie

Une étude prospective de traitement du syndrome de la vestibulite vulvaire

Chercheurs principaux
Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard Glazer,
Mme Sophie Bergeron et Mme Janet Bradley

FORMULAIRE DE CONSENTEMENT #2

But de l'étude

La présente étude a pour but d'examiner l'efficacité de trois modalités de traitement de la vestibulite vulvaire (douleur pendant les relations sexuelles): 1) la vestibulectomie (chirurgie), 2) la gestion de la douleur en groupe, et 3) la rétroaction biologique (biofeedback). Un second objectif de l'étude est d'examiner les facteurs associés à un résultat de traitement positif. Cette démarche vers une meilleure compréhension de la douleur pendant les relations sexuelles vise à aider les professionnels de la santé à développer des traitements plus efficaces pour les femmes qui souffrent de ce problème frustrant et dérangeant.

Procédures

La participante sera assignée au hasard à un des traitement suivants: 1) vestibulectomie, 2) gestion de la douleur en groupe, ou 3) rétroaction biologique. Ceci signifie qu'elle ne pourra pas choisir le traitement qu'elle recevra; c'est le hasard qui déterminera quel traitement elle va recevoir. Tous les traitements inclus dans cette étude sont des traitements réguliers pour le syndrome de la vestibulite vulvaire.

Vestibulectomie Une vestibulectomie est une procédure chirurgicale mineure lors de laquelle on excise superficiellement la région vulvaire douloureuse, qui est ensuite recouverte par la partie inférieure du vagin. Cette chirurgie cause moins de dommages à la

région vulvaire qu'un simple accouchement. La vestibulectomie est le traitement le plus fréquemment utilisé pour enrayer la douleur occasionnée par la vestibulite vulvaire. Les études portant sur ce traitement démontrent que 60 à 85% des femmes qui subissent une vestibulectomie bénéficient d'une amélioration significative ou d'un soulagement complet de leur douleur. Je comprends que si je suis assignée à ce traitement, cela nécessitera une visite à la clinique de pré-admission pour un examen physique afin d'évaluer mon état médical général et de faire faire des prises de sang. La quantité totale de sang qui sera prélevée équivaut environ à 30 ml (6 cuillères à thé). Ces prises de sang font partie de la procédure normale et comprennent une CSC (culture de sang complète) semblable à celle que j'aurais lors d'un examen médical annuel avec mon médecin de famille, la mesure des électrolytes du sérum, et une identification de mon groupe sanguin. Il est possible que ces prises de sang occasionnent certains inconforts tels des ecchymoses et de l'infection, quoique cela soit très rare. Cette procédure de pré-admission est la même pour tous les patients subissant une anesthésie à l'Hôpital Royal Victoria. La chirurgie elle-même dure environ 45 minutes et sera effectuée sous anesthésie générale par Dr. Khalifé ou Dr. Pagidas. Je comprends que la chirurgie comporte certains risques. Il y a une faible chance que j'aie des saignements excessifs, des infections, des hématomes (effusion de sang dans le tissu vulvaire), une fistule uréthrovaginale (ouverture anormale entre l'urètre et le vagin) ou une fistule rectovaginale (ouverture anormale entre le rectum et le vagin). Le risque de développer une de ces complications est de moins de 1%. S'il arrivait que j'aie une complication, je contacterais mon chirurgien qui traiterait la complication immédiatement. Il existe un traitement médical et /ou chirurgical sécuritaire pour toutes les complications possibles. Je peux consulter Dr. Khalifé ou Dr. Pagidas pour obtenir plus d'informations concernant les traitements pour ces complications. Je comprends également que l'usage de l'anesthésie comporte certains risques. L'anesthésie générale est parfois suivie d'une brève période de nausée. Les problèmes sérieux sont extrêmement rares et sont généralement causés par un manque d'oxygène. Les chances de mourir d'une anesthésie, peu importe quel type, sont extrêmement rares, environ 1 sur 200 000. Aucune de ces morts n'est survenue à l'Hôpital Royal Victoria dans les derniers 25 ans. Après la chirurgie, on me donnera des instructions post-opératoires générales, ainsi que des instructions qui aideront à faciliter la guérison de la région douloureuse. Je peux quitter l'hôpital 2-3 heures après la fin de la chirurgie. Il serait préférable que je demande à quelqu'un de m'accompagner ou de me reconduire chez moi puisqu'il peut y avoir encore des effets mineurs de l'anesthésie tels la fatigue et un temps de réaction plus lent. Ces effets, s'ils ont lieu, devraient être complètement disparus 5-6 heures après la fin de la chirurgie. Je comprends que je vais peut-être ressentir de la douleur vulvaire durant la semaine suivant la chirurgie, quoique

ceci n'aura pas nécessairement lieu. Si en effet je ressens de la douleur à ce moment, elle ne durera pas plus d'une semaine. D'une façon ou d'une autre, on me donnera des analgésiques (anti-douleur) après la chirurgie, dont le coût sera défrayé par les chercheurs. La guérison complète de la région prendra environ de 8 à 12 semaines. Je pourrai reprendre mes relations sexuelles 12 semaines après la chirurgie. Je pourrai retourner au travail 2 jours après la chirurgie.

Rétroaction biologique Le but de la rétroaction biologique (biofeedback) est d'entraîner les femmes qui souffrent de douleur pendant les relations sexuelle à acquérir un meilleur contrôle de leurs muscles vaginaux hypertendus, tension qui peut jouer un rôle dans le maintien de la douleur. Une étude récente a démontré que 52% des femmes qui subissent un traitement de biofeedback bénéficient d'un soulagement complet de leur douleur et que la diminution moyenne de la douleur de toutes les participantes est de 83%. Le biofeedback nécessite que la participante s'insère elle-même un petit détecteur EMG (environ 1 1/2 pouce de long and 1 pouce de large) dans le vagin. L'insertion du détecteur a lieu dans la salle de bain privée de la chambre d'examen. Je comprends que je serai complètement vêtue durant les sessions d'entraînement de biofeedback. Lors de la première session, une première évaluation de la tension musculaire des muscles du vagin sera effectuée. La suite du traitement implique la pratique quotidienne d'une série d'exercices de contraction/relaxation musculaire, en adaptant les contractions au feedback du thérapeute et de l'écran d'ordinateur, basé sur la mesure de la tension musculaire vaginale. Le thérapeute qui me donnera mon entraînement de biofeedback sera un psychologue possédant une maîtrise ou un doctorat. Des sessions d'une heure d'entraînement au biofeedback seront données 1 fois/semaine pendant les 4 premières semaines de traitement. Ces sessions seront ensuite données 1fois/2 semaines pour une période de 8 semaines, pour un total de 8 sessions d'entraînement durant une période de 12 semaines. Toutes les sessions auront lieu à l'Hôpital Royal Victoria. Ce traitement inclut aussi un entraînement à l'utilisation d'un appareil EMG portatif qui servira pour les exercices à la maison
(deux sessions de 20 minutes par jour, 6 jours/semaine, pour un total de 4 heures/semaine de pratique). Les chercheurs défraieront les coûts du EMG portatif. Le traitement de biofeedback ne me causera pas plus de douleur qu'à l'habitude.

Groupe de gestion de la douleur Des exercices dérivés des techniques de thérapie sexuelle ont été utilisés pour réduire l'anxiété et le manque d'excitation associés avec la douleur pendant les relations sexuelles. Les chercheurs croient que ces techniques affectent également une composante physique telle la relaxation des muscles du vagin. Des études

ont démontré que 43 à 68% des femmes qui pratiquent des techniques de thérapie sexuelle bénéficient d'une amélioration significative ou d'un soulagement complet de leur douleur. La gestion de la douleur en groupe consistera en une série de sessions de groupe d'une durée de 2 heures chacune (7-8 femmes par groupe). Ces sessions auront lieu 1 fois/semaine pour les 4 premières semaines et seront dirigées par un psychologue détenant une maîtrise ou un doctorat. Les sessions seront ensuite données 1 fois/2 semaines pour une période de 8 semaines. Toutes les sessions auront lieu à l'Hôpital Royal Victoria. Le traitement incluera les éléments suivants: éducation et information concernant la douleur et la sexualité, éducation concernant l'anatomie sexuelle, des techniques de relaxation, des exercices Kegel, des exercices de dilatation vaginale et de la restructuration cognitive (remplacer des pensées erronnées ou irrationnelles au sujet de la douleur et de la sexualité par des pensées plus réalistes). L'utilisation de ces techniques comporte des exercices à la maison sur une base hebdomadaire (1 heure par semaine). Le traitement par la gestion de la douleur ne me causera pas plus de douleur qu'à l'habitude. Je comprends que je ne serai obligée à aucun moment de discuter de quoi que ce soit à mon sujet que je ne désire révéler.

Enregistrement vidéo

Je comprends que certaines sessions des traitements de biofeedback et de gestion de la douleur seront filmées à l'aide d'une caméra vidéo pour les buts de l'étude. Ceci ne nécessitera pas de caméraman; la caméra vidéo sera sur un trépied. L'accès à ces vidéos sera strictement réservé aux membres de l'équipe de recherche. Les vidéos seront conservés dans un classeur verroullé pendant 3 ans après la fin de l'étude; ils seront ensuite effacés. Des doubles de ces vidéos seront conservés dans un autre classeur verrouillé et seront eux aussi effacés 3 ans après la fin de l'étude. Je comprends que je devrai signer un formulaire de consentement du Centre audio-visuel de l'Hôpital Royal Victoria en rapport avec cet enregistrement vidéo.

Procédures d'évaluation

Je comprends que ma participation à l'étude inclut deux autres évaluations, toutes deux similaires à la première évaluation à laquelle j'ai pris part, quoique de plus courte durée. Celles-ci auront lieu respectivement après 12 semaines de traitement (fin du traitement), et 6 mois après la fin du traitement. J'accepte librement de participer à ces 2 évaluations, chacune incluant une entrevue dirigée et des questionnaires concernant ma douleur pendant la pénétration, ma sexualité, mes attitudes sexuelles, ma(mes) relations amoureuse(s) et mes symptômes physiques et psychologiques actuels (durée=60 min.), ainsi que 2 examens gynécologiques réguliers qui pourraient inclure des cultures vaginale, cervicale et

une culture d'urine, si indiqué. Dans ce cas, le gynécologue prendrait un prélèvement du col de l'utérus et un autre du vagin, et ceci avec un Q-tip. Cette procédure ne durera que quelques secondes et ne causera aucune douleur (semblable à un Pap test). La culture d'urine nécessite la production d'un échantillon d'urine en privé.

J'accepte librement de noter ma douleur quotidiennement sur une feuille d'auto-observation (Inventaire quotidien de la douleur) 2 semaines par mois pendant le traitement, ainsi que 2 semaines par mois pendant les 6 mois suivant la fin du traitement (les 6 mois entre l'évaluation de fin de traitement et l'évaluation finale).

J'accepte librement de discontinuer l'utilisation de tout autre type de traitement pour la durée totale de l'étude, soit une durée de 9 mois: 3 mois de traitement, et 6 mois de suivi, après quoi je prendrai part à l'évaluation finale de ma douleur. Cette procédure a pour fonction d'assurer que les résultats de l'étude seront effectivement dûs au traitement administré pendant la période de 12 semaines plutôt qu'à d'autres traitements que j'aurais pu employer pendant la période de 9 mois de ma participation à l'étude.

Je comprends que les résultats des évaluations seront inscrits dans deux dossiers: le premier, qui incluera les cultures et les résultats des examens gynécologiques, demeurera à l'hôpital et sera identifié par mon nom. Le second dossier, qui incluera l'entrevue dirigée, les questionnaires ainsi que les résultats des examens gynécologiques, demeurera à la disposition de l'équipe de recherche seulement et sera identifié uniquement par un numéro.

Bénéfices et risques

Je comprends que si le traitement de ma douleur vulvaire ne donne pas de résultats satisfaisants, on m'offrira d'autres options de traitement par les services habituels de l'hôpital, tels les 2 autres traitements étudiés dans le cadre de ce projet.

Il est entendu que je ne suis nullement obligée de participer à cette étude. De plus, je demeure libre de me retirer de cette étude en tout temps ou de refuser de répondre à n'importe quelle question, et ce, sans avoir à fournir d'explication. Je peux recevoir un traitement approprié sans prendre part à l'étude, par les services réguliers de l'hôpital.

J'accepte librement de participer au projet de recherche intitulé "Une étude prospective de traitement du syndrome de la vestibulite vulvaire ", projet entrepris par Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Dr. Howard Glazer, Mme Sophie Bergeron et Mme

Janet Bradley, principaux chercheurs, ainsi que le Département d'Obstétrique et de Gynécologie et le Service de thérapie sexuelle et de thérapie de couple de l'Hôpital Royal Victoria, de même que le Département de Psychologie de l'Université McGill (398-6094).

Advenant que j'aie des plaintes ou des insatisfactions par rapport à cette recherche, je sais que je peux les communiquer à un des chercheurs principaux ou à Dr. Dennis Kalogeropoulos, Directeur Associé du Service de thérapie sexuelle et de thérapie de couple de l'Hôpital Royal Victoria (tél.: 842-1231, poste 4284).

Si j'ai des questions concernant mes droits comme sujet de recherche, je peux m'adresser au Représentant des Patients au 842-1231, poste 5655.

Une copie de ce formulaire de consentement me sera remis pour mes dossiers personnels et pour référence future.

Signature _____

Nom (lettres moulées) _____

Date _____

Témoin _____

Dr. Irv Binik _____

Appendix 5 - Information for Potential Participants

Randomized Treatment Outcome Study

Answers to some of your questions...

What is Vulvar Vestibulitis Syndrome?

Vulvar Vestibulitis Syndrome (VVS) is a chronic, persistent gynecological condition characterized by pain on attempted vaginal entry (intercourse, tampon insertion, gynecological exams, etc.), significant pain to a Q-tip palpation of the vestibule (entry of vagina), and physical findings limited to increased redness (irritation) of the vulva. It is one of the major causes of painful intercourse in women under 40. It is suspected to be increasingly common, with rates of up to 15% in a general gynecological practice. Little is known about what causes VVS; it has been linked to repeated vaginal infections. Researchers have only begun to study it seriously about 10 years ago, and clinicians are only beginning to find out about its existence. A review of all the scientific articles published on the topic can be made available to you if you are interested in finding out more about VVS.

What is the Vulvar Vestibulitis Syndrome Treatment Study?

It is a large-scale study put together by a multidisciplinary team of researchers and clinicians specialized in painful intercourse (dyspareunia) and funded by Health Canada and Pfizer company. This team has conducted another large-scale study on painful intercourse in which over a 100 women participated. The present study is designed to investigate the relative effectiveness of three different treatments for Vulvar Vestibulitis Syndrome: 1) vestibulectomy (minor surgery), 2) pain management, and 3) biofeedback. Ninety women from the Montreal area will take part in this treatment study.

How long is the study?

The study will last 9 months: during the first 3 months, you will be undergoing treatment (one of the three treatments mentioned above) and monitoring your pain 2 weeks per month. During the following 6 months (which we call the *follow-up period*), you will keep monitoring your pain 2 weeks per month. This monitoring is the same as the one you did during the first part of the study, right after your first gynecological assessment.

What about my time?

The time required for each treatment is explained clearly in the accompanying consent form. Aside from that, you will be asked to come in to the hospital for another assessment of your pain (similar to the first one but shorter) immediately following the 3-month treatment period, and also after the 6-month follow-up period. These assessments will involve an

interview and 2 gynecological exams. Throughout the study, you will be monitoring your pain 2 weeks per month, and this takes about 2 minutes per day. We will reimburse you for your transportation expenses up to a maximum of 50$.

Why can't I choose my treatment?

Assigning every participant randomly to one of 3 treatment conditions allows to evaluate the effectiveness of each treatment with a maximum of objectivity. Otherwise, the different treatment groups would not be comparable and this would introduce bias in the analysis of the effectiveness of the treatments. We would never be able to know if it is the treatment that is effective, or if it is some other factor or characteristic that is responsible for the improvement of the participants. For this same reason, Janet Bradley, the research coordinator who conducts the interviews and organizes the assessments, will not be informed of what treatment you are assigned to.

What are the benefits?

1. Regular gynecological exams and laboratory examinations, thus close attention given to your problem by a team of dedicated experts.
2. All services related to the Vulvar Vestibulitis Treatment Study are provided at no cost to you.
3. An opportunity for you to receive one of three cutting-edge treatments, one of which is not offered elsewhere in Canada (biofeedback).
4. An opportunity for you to participate in a large-scale study which could have a major impact on the treatment of painful intercourse in our society.

Why get involved?

This research program is a major effort aimed directly at treating pain during intercourse. Your participation will help make it work. You can personally benefit from this study, and other women currently suffering from this problem as well as future generations of women may also greatly benefit from your involvement.

This information sheet was conceived by the principal researchers: Dr. Irving Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Ms Sophie Bergeron and Mrs. Janet Bradley.

Réponses à quelques-unes de vos questions...

Qu'est-ce que le syndrome de la vestibulite vulvaire?
Le syndrome de la vestibulite vulvaire (SVV) est une condition gynécologique chronique et persistante charactérisée par la présence de douleur lors d'un essai de pénétration vaginale (relations sexuelles, tampons, examens gynécologiques, etc.), une douleur significative lors d'une palpation du vestibule (entrée du vagin) avec un *Q-tip*, et des symptômes physiques limités à une rougeur (irritation) de la vulve. C'est une des causes principales de douleur pendant la pénétration chez les femmes de moins de 40 ans. Plusieurs femmes souffrent de ce problème, soit jusqu'à 15% des femmes consultant un gynécologue. On connaît peu de choses au sujet du SVV; il a été lié à des infections vaginales répétées. Les chercheurs ont seulement commencé à étudier ce problème de façon sérieuse il y a 10 ans, et les cliniciens commencent seulement au courant de son existence. Une revue de la documentation portant sur le SVV peut vous être procurée si vous désirez en savoir plus sur ce problème.

Qu'est-ce que l'Étude de traitement du syndrome de la vestibulite vulvaire?
C'est une étude majeure mise sur pied par une équipe multidisciplinaire composée de chercheurs et de cliniciens spécialistes de la douleur pendant les relations sexuelles (dyspareunie). Ce groupe est subventionné par Santé Canada et par la compagnie Pfizer. Cette équipe a déjà effectué une autre étude portant sur la douleur pendant les relations sexuelles à laquelle plus de 100 femmes ont participé. L'objectif de a présente étude est d'évaluer l'efficacité de trois traitements du syndrome de la vestibulite vulvaire: 1) vestibulectomie (chirurgie mineure), 2) gestion de la douleur, and 3) rétroaction biologique (biofeedback). Quatre-vingt-dix femmes de la région de Montréal prendront part à la présente étude de traitement.

Quelle est la durée de l'étude?
L'étude durera 9 mois: durant les 3 premiers mois, vous allez participer à un traitement (un des trois traitements ci-haut mentionnés) et remplir des fiches d'auto-évaluation de votre douleur deux semaines par mois. Durant les 6 mois suivants (que nous appelons la *période de suivi*), vous allez continuer de remplir des fiches d'auto-évaluation deux semaines par mois. Cette auto-évaluation est la même que celle que vous avez effectuée pendant la première étape de l'étude, tout de suite après votre premier examen gynécologique.

Combien de temps devrai-je y consacrer?

Le temps requis pour chaque traitement est expliqué clairement dans le formulaire de consentement ci-joint. Mis à part votre participation au traitement, on vous demandera de vous présenter à l'hôpital pour une autre évaluation de votre douleur (semblable à la première mais plus courte) immédiatement après la fin des 3 mois de traitement (évaluation post-traitement), et une dernière fois après la période de suivi de 6 mois (évaluation de suivi). Ces évaluations comporteront une entrevue et 2 examens gynécologiques. Tout au long de l'étude, vous allez remplir des fiches d'auto-évaluation 2 semaines par mois, et ceci prend environ 2 minutes par jour. Nous vous rembourserons vos frais de transport jusqu'à un maximum de 50$.

Pourquoi ne puis-je choisir mon traitement?

Assigner chaque participante au hasard à un des 3 traitements permet d'évaluer l'efficacité de chaque traitement avec un maximum d'objectivité. Autrement, les différents groupes de traitement ne seraient pas comparables et cela introduirait un biais dans l'analyse de l'efficacité des traitements. Nous ne pourrions donce pas savoir si c'est le traitement qui est efficace ou si l'amélioration des participantes est due à un autre facteur. Pour cette même raison, Janet Bradley, la coordonatrice de recherche qui effectue les entrevues et qui organise les évaluations, ne sera pas informée du traitement auquel vous serez assignée.

Quels sont les bénéfices?

1. Des examens gynécologiques et des analyses en laboratoire effectués sur une base régulière, donc une attention soutenue portée à votre problème par une équipe d'experts dévoués.
2. Tous les services en rapport avec l'Étude de traitement du syndrome de la vestibulite vulvaire vous sont offerts gratuitement.
3. Une opportunité pour vous de recevoir un traitement parmi trois qui sont tous à la fine pointe des connaissances scientifiques, dont un n'est offert nulle part ailleurs au Canada (biofeedback).
4. Une opportunité pour vous de participer à une étude majeure qui aura un impact très important sur le traitement des relations sexuelles douloureuses dans notre société.

Pourquoi m'impliquer?

Ce programme de recherche constitue un effort majeur dont l'objectif premier est le traitement de la douleur pendant les relations sexuelles. Votre participation aidera à sa mise sur pied. Vous pouvez bénéficier personnellement de cette étude et d'autre femmes

souffrant présentementand de ce problème ainsi que celles des générations futures pourront aussi grandement bénéficier de votre participation à ce projet.

Ce feuillet d'information a été conçu par les chercheurs principaux: Dr. Irv Binik, Dr. Samir Khalifé, Dr. Kelly Pagidas, Mme Sophie Bergeron et Mme Janet Bradley

Appendix 6 - Pre-Treatment Structured Interview

Randomized Treatment Outcome Study

STRUCTURED INTERVIEW

WOMEN

Subject Number _____

Referred from _____

Interviewer _____

Date of interview _____

SOCIO-DEMOGRAPHIC INFORMATION

1) Date of birth ____/_____/____
mo day year

2) Place of birth

1) Canada
2) United States
3) Western Europe
4) Eastern Europe
5) African
6) Asian
7) Australia
8) Middle East
9) Latin America/South America
10) Caribbean

3) What culture do you see yourself as most associated with?

1) French Canadian
2) English Canadian
3) American
4) Western European
5) Eastern European
6) African
7) Asian
8) Australian
9) Middle Eastern
10) Latin American/South American
11) Caribbean

4) What is your mother tongue? _____

5) In what religion were you brought up? _____

6) How many years of schooling do you have? _____

7) What is the approximate total annual income of your household?

a) $000 - $9,999
b) $10,000 - $19,999
c) $20,000 - $29,999
d) $30,000 - $39,000
e) $40,000 - $49,999
f) $50,000 - $59,000
g) $60,000 and over

RELATIONSHIP HISTORY

1) Which of the following best describes your current situation?

a) no regular partner at the moment
b) dating one partner regularly
c) living with a partner
d) married

2) How long have you been in the situation you circled above?

_____ years _____ months

3) If you have a partner, please state how old he is. _____ years

4) Would your partner be willing to participate in this study? YES NO

5) Have you experienced childbirth? YES NO

If yes, please specify # of children _____

6) How many times have you been legally separated or divorced ? _____

7) Have you ever been widowed? YES NO

8) How many partners have you lived with or been married to? _____

9) How many romantic relationships have you had in your life that you have considered serious relationships? _____

10) What is the total number of partners you have had intercourse with? (Include one-night stands) _____

11) How old were you when you had intercourse for the first time? _____ years

12) Do you remember it as being painful? YES NO

13) Was it the same pain as the one you experience now? YES NO

GYNECOLOGICAL HISTORY

1) Which of the following best describes your situation in terms of menstruation in the past 6 months?

a) I menstruate regularly
b) I have an irregular cycle
c) My periods are irregular because I am approaching menopause
d) I do not menstruate because I am breast feeding
e) I do not menstruate because I had a partial hysterectomy
f) I do not menstruate because I had a total hysterectomy
g) I do not menstruate because I am post-menopausal
h) Other. Please specify _____

2) **If you are still menstruating** please rate on the following scale the pain you experience during your menstrual periods.

0 1 2 3 4 5 6 7 8 9 10
no pain worst pain ever

3) **If you are post-menopausal,** please state when you had your last period.

_____/_____
mo yr.

4) **If you are post-menopausal,** are you on hormone replacement therapy? YES NO

If so, a) since when? _____/_____
mo yr.

b) What are you currently taking? _____

c) What dosage do you take? _____

d) Were you ever on some other form of hormone replacement therapy? YES NO

If so, please state i) what kind _____
ii) what dosage _____
iii) what length of time _____

If not, have you ever been? YES NO

5) If you took hormones and stopped, please state the reason why.

_____

6) Have you ever taken contraceptive pills? YES NO

7) If yes, at what age did you first take them ? _____ years

8) If yes, please state the total number of years and months in your life during which you were taking contraceptive pills.

_____ months _____ years

9) Which of the following best describes your situation at the moment in terms of contraception? (please circle as many as apply)

a) Douche
b) Spermicide jelly or foam
c) Condoms
d) Diaphragm
e) Cervical cap
f) Sponge
g) IUD
h) The pill
i) Morning-after pill
j) Tubal ligation (tubes tied)
k) Hysterectomy
l) Partner has vasectomy
m) You are infertile
n) Partner is infertile
o) You no longer have periods due to menopause
p) Rhythm method (abstain when ovulating)
q) Partner exits before ejaculating
r) No contraceptive measures taken but do not want to get pregnant
s) Trying to get pregnant
t) You are pregnant
u) You are breast-feeding
v) Do not engage in intercourse at all
w) No partner/no measures
x) Other. Please specify

_____

_____

FOR WOMEN WHO HAVE EXPERIENCED CHILDBIRTH (# 10, 11, 12)

10) How many cesarean deliveries have you had? _____

11) How many deliveries aided by an episiotomy have you had? _____

12) How many deliveries have you had in which your vagina tore? _____

13) How many miscarriages have you had? _____

14) How many abortions have you had? _____

15) How many yeast or other vaginal infections have you had in the last 2 years? _____

a) What treatments did you use? _____

b) How were they diagnosed? i) clinical plus positive culture
ii) clinical only
iii) self-diagnosed

16) Have you had repeated yeast infections in the past? YES NO

17) How many bladder/urinary infections (cystitis) have you had in the last 2 years?

_____

a) What treatments did you use? _____

b) How were they diagnosed? i) clinical plus urinalysis
ii) clinical only
iii) other (please specify) _____

18) Have you had repeated bladder/urinary infections (cystitis) in the past? YES NO

19) How often do you urinate in one day? _____

20) Have you ever suffered from any of the following sexually transmitted diseases? (Please check if applicable)

Chlamydia _____
Gardnerella vaginalis _____
Genital herpes _____
Genital warts _____
Gonorrhea _____
H.I.V _____
Syphilis _____
Trichomoniasis _____
Other _____ Please specify _____

21) Have you ever suffered from pelvic inflammatory disease?
YES, now
YES in past
NO

22) Have you ever had endometriosis?
YES now
YES in past
NO

23) Have you had any of the following gynecological/ genital surgeries? If so, when?

Hysterectomy _____	Year _____
Laparoscopy _____	Year _____
Ovariectomy _____	Year _____
Tubal ligation _____	Year _____
Laser for condyloma _____	Year _____
Other _____	Year _____

PAIN HISTORY

1) When did you first start experiencing pain with intercourse?

_____ month _____ year

2) How did it start?

a) with first intercourse
b) after repeated candidal infections
c) after childbirth
d) for no apparent reason
e) change of partner
f) after repeated bladder infections
g)with onset of menopause
h) after gynecological surgery
i) life stress (e.g. marital conflict, financial problems)
j) after an abortion
k) other _____

3) Have you always felt pain during intercourse since your first experience of pain with intercourse?

a) yes
b) no, it depended on the partner
c) no, when I stopped taking the pill, it went away
d) no, it came and went without any apparent reason
e) no, after childbirth, it stopped temporarily and then came back
f) no, after treatment _____, it stopped and then came back
g) no, other _____

4) Have you had more than one partner since the pain started? YES NO

5) How many health professionals have you consulted for the pain? _____

6) What diagnoses and treatments were you given by the health professionals to whom you reported the pain?

Please list the name of every diagnosis, medication/treatment you remember receiving and the number of times you took/underwent the prescribed treatment.

Diagnosis	Treatment	Number of times taken
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

7) I) Have you ever attempted to treat or alleviate the pain in any of the following ways?

Check off specific method tried (e.g. changing mattress)

II) How much has it helped on a scale from 0 (not at all) to 10 (cured)

a) a variety of small measures
wearing cotton underwear _____
using mild soaps or no soap at all _____
special baths _____
changing your mattress _____
other (please specify) _____

_____

b) changing aspects of your sex life
intercourse positions _____
asking your partner to go more slowly _____
trying to enhance arousal by prolonging foreplay _____
trying to enhance arousal by wearing sexy clothing _____
trying to enhance arousal by watching erotic film _____
being more sexually assertive _____
changing partners _____
other (please specify) _____

_____

c) trying a variety of creams
applying lubricant (e.g. K-Y or Crisco) to yourself or your partner _____
applying moisturizing cream (e.g. Prevex) _____
applying corticosteroid cream as prescribed by a doctor _____
applying an anesthetic jelly (e.g. Xylocaine to freeze the area) _____
applying hormonal cream (e.g. Premarin) _____
antifungal cream _____
other (please specify) _____

_____

d) alternative medicine
supplemental vitamins (e.g. vitamin E) _____
special diet (e.g. low in calcium oxalate, low sugar etc.) _____
homeopathic remedies (e.g. herbs or natural solutions) _____
physiotherapy _____
osteopathy _____
acupuncture _____
massage therapy _____
other (please specify) _____

_____

e) psychological treatments
individual psychotherapy _____
marital/couple therapy _____
sex therapy _____
hypnosis, relaxation _____

Kegel and dilatation exercises _____
biofeedback _____
other (please specify) _____

_____

f) other medical treatments
taking hormones orally (e.g. hormone pills e.g., Premarin/Provera) _____
antibiotics _____
systemic antifungals _____
systemic antivirals _____
interferon injections _____
other (please specify) _____

_____

g) surgery
D&C _____
laser _____
vestibulectomy _____

_____

h) other (please specify) _____

_____

9) Has any other member of your family suffered from the same problem?
YES NO Not discussed
If yes, what relationship to you? _____

10) Have you ever experienced an incident/illness involving vulvar pain in the past ?
YES NO

Please specify _____

(all women presently having intercourse)

PAIN

1) Over the past 6 months approximately how many times have you **attempted** to have intercourse per month? _____ (IF ANSWER = 0 proceed to page 14)

2) In the past 6 months, have you ever experienced pain or significant discomfort before, during or after intercourse? YES NO If no, SKIP TO Q-5

3) Why do you think you have pain with intercourse? What is your personal theory about your discomfort?

_____
_____
_____
_____

4) In the past 6 months approximately how many times per month has your partner's erect penis been able to enter your vagina (succeeded in having intercourse)?
_____ times per month.

5) Over the past 6 months, what is the average length of time that your partner's erect penis is in your vagina ? _____ minutes

6) In the last 6 months approximately how many times per month do you experience pain due to intercourse? _____ times per month.

7) When you do have pain, is the pain always of the same intensity or does it vary?

YES NO (it varies)

8) **If applicable:** Is there anything special about the times when you have less or no pain? Are there any special circumstances you can identify ? Please check off any of the following that apply or specify circumstances not listed.

It depends on (put check mark on as many as apply)

How tired I am _____
How lubricated I am _____
The intercourse position we use _____
How nervous or anxious I am _____
The partner I am having sex with _____
Whether we are alone in the house _____
The time of day _____
The length of time since the last episode of intercourse _____
How aroused I am _____
How long foreplay lasts _____
The place where we have intercourse ____
The time of my menstrual cycle _____
Whether I am angry with my partner _____
Whether I have taken any drugs _____
Whether I have had an alcoholic beverage __
How long we had been having intercourse _
Other _____ (please specify) _____

9) When does the pain typically start?

a) before penis touches vaginal opening
b) when penis starts to enter vagina
c) when penis has fully entered and is thrusting
e) within 1/2 hour after intercourse
f) more than 1/2 hour after intercourse
g) other. Please specify _____

_____

10) How long does the pain typically last ?

a) during penile entry only
b) during the penile thrusting only
c) only for a period after penile exit
d) during penile entry and after penile exit
e) during penile entry and during penile thrusting
f) during penile thrusting and for some time after penile exit
g) during penile entry, during penile thrusting and after penile exit
h) it is never the same: there is no typical pattern

If it lasts after penile exit, please state for how long after, the pain is felt

Time: _____ minutes _____ hours _____ days

11) Where do you typically feel the pain during intercourse? Is there a specific spot you can show me? If yes, where ? (You may select more than one)
(Show model and code on the diagram)

a) at the vaginal opening
b) everywhere on the vulva
c) inside the vagina
d) in the pelvic or abdominal region

<u>vestibule</u>

12

9-12 ___ ___ 12-3

6-9 ___ ___ 3-6

6

12) Rate the average intensity of the pain at the entry and/or lower part of the vagina (past 6 months) on a scale of 0 to 10

0 1 2 3 4 5 6 7 8 9 10
no pain worst pain ever

13) Rate the average intensity of the pain in the pelvic or abdominal region (past 6 months) on a scale of 0 to 10

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

14) In the past 6 months have you regularly experienced pain in your genital area in any of the following situations?

a) Friction with clothing _____
b) Urinating in general _____ Urinating after intercourse _____
c) Inserting a tampon _____
d) Removing a tampon _____
e) Masturbating alone _____
f) Partner stimulating you manually _____
g) Partner stimulating you orally _____
h) Finger insertion _____
i) Standard gynecological examination _____
j) Sporting activity (please specify) _____
k) Pain not related to any specific activity _____
l) Other _____ please specify _____

15) Do you **regularly** suffer from any of the following pains? Please check off as many of the following as apply.

Neck pain ___
Pain in kidneys ___
Sore throat ___
Toothaches ___
Earaches ___
Other _____ Please specify _____

(women not having intercourse now)

PAIN

1) How long has it been since the last time you had intercourse?

_____ months _____ years

2) What is the reason you have not had intercourse in the past 6 months?

a) I have no partner at the moment
b) it hurts too much
c) I have no desire
d) my partner has erection problem
e) my partner has no desire
f) my partner is concerned about hurting me
g) other _____

3) Do you want to resume intercourse? YES NO

4) When you had intercourse in the past did you ever experience pain or significant discomfort before, during or after intercourse? YES NO If no skip to Q-20

5) Why do you think you have pain with intercourse? What is your personal theory about your discomfort?

_____
_____
_____
_____

6) In the past approximately how many times per month were you **attempting** to have intercourse ? _____

7) In the past approximately how many times per month has your partner's erect penis been able to enter your vagina (succeeded in having intercourse)? _____ times per month.

8) What was the average length of time that your partner's erect penis was in your vagina ? _____ minutes

9) How many times per month did you experience pain due to intercourse? _____ times per month.

10) When you do have pain, is the pain always the same intensity or does it vary?

YES NO (it varies)

11) **If applicable:** Is there anything special about the times when you have less or no pain? Are there any special circumstances you can identify ? Please check off any of the following that apply or specify circumstances not listed.

It depended on (put check mark on as many as apply)

How tired I was _____ How aroused I was _____
How lubricated I was _____ How long foreplay lasted _____
The intercourse position we used _____ The place where we had intercourse ____
How nervous or anxious I was _____ The time of my menstrual cycle _____
The partner I was having sex with _____ Whether I was angry with my partner _____
Whether we were alone in the house _____ Whether I had taken any drugs _____
The time of day _____ Whether I had an alcoholic beverage ___
The length of time since the last episode of intercourse _____
How long we had been having intercourse for _____
Other _____ (please specify) _____

12) When did the pain typically start?

a) before penis touched vaginal opening
b) when penis started to enter vagina
c) when penis had fully entered and is thrusting
e) immediately after intercourse
f) more than 1/2 hour after intercourse
g) other. Please specify _____
_____

13) How long did the pain typically last ?

a) during penile entry only
b) during penile thrusting only
c) only for a period after penile exit
d) during penile entry and after penile exit
e) during penile entry and during penile thrusting
f) during penile thrusting and for some time after penile exit
g) during penile entry, during penile thrusting and after penile exit
h) it was never the same; there is no typical pattern

If it lasted after penile exit, please state for how long after, the pain was felt

Time: _____ minutes _____ hours _____ days

14) Where did you typically feel the pain during intercourse? Is there a specific spot you can show me? If yes, where ? (You may select more than one)

(Show model and code on the diagram on next page)

a) at the vaginal opening
b) everywhere on the vulva
c) inside the vagina
d) in the pelvic or abdominal region

vestibule

12

9-12 ___ ___ 12-3

6-9 ___ ___ 3-6

6

15) Rate the intensity of the pain at the entry and/or lower part of the vagina on this scale of 0 to 10

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

16) Rate the intensity of the pain in the pelvic or abdominal region on this scale of 0 to 10

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

17) Have you ever regularly experienced pain in your genital area in any of the following situations?

a) Friction with clothing _____
b) Urinating in general _____ Urinating after intercourse _____
c) Inserting a tampon _____
d) Removing a tampon _____
e) Masturbating alone _____
f) Partner stimulating you manually _____
g) Partner stimulating you orally _____
h) Finger insertion _____
i) Standard gynecological examination _____
j) Sporting activity (please specify) _____
k) Pain not related to any specific activity _____
l) Other _____ please specify _____

18) Do you **regularly** suffer from any of the following pains? Please check off as many of the following as apply.

Neck pain ___
Pain in kidneys ___
Sore throat ___
Toothaches ___
Earaches ___
Other _____ Please specify _____

ENTREVUE DIRIGÉE

FEMMES

Numéro du sujet _____

Référée par _____

Intervieweur _____

Date de l'entrevue _____

INFORMATION SOCIO-DÉMOGRAPHIQUE

1) Date de naissance ____/_____/____
mois jour année

2) Lieu de naissance

1) Canada
2) Etats-Unis
3) Europe de l'Ouest
4) Europe de l'Est
5) Afrique
6) Asie
7) Australie
8) Moyen-Orient
9) Amérique Latine /Amérique du Sud
10) Caraïbbes

3) Quelle est la culture à laquelle vous vous sentez le plus étroitement liée?

1) Québécoise
2) Canadienne Anglaise
3) Américaine
4) Européenne de l'Ouest
5) Européenne de l'Est
6) Africaine
7) Asiatique
8) Australienne
9) Moyen-Orient
10) Latino-Américaine/Sud-Américaine
11) Caraïbbes

4) Quelle est votre langue maternelle? _____

5) Dans quelle religion avez-vous été élevée?_____

6) Combien d'années de scolarité avez-vous? _____

7) Quel est le revenu annuel approximatif de votre ménage?

a) $000 - $9,999
b) $10,000 - $19,999
c) $20,000 - $29,999
d) $30,000 - $39,000
e) $40,000 - $49,999
f) $50,000 - $59,000
g) $60,000 et plus

HISTOIRE RELATIONNELLE

1) Lequel des points suivants décrit le mieux votre statut civil actuel?

a) célibataire non engagée dans une relation
b) célibataire avec un partenaire régulier
c) en union de fait
d) mariée depuis

2) Depuis combien de temps êtes-vous dans la situation encerclée ci-dessus?

_____années _____mois

3) **Si vous avez un partnenaire**, quel âge a-t-il? _____ ans

4) **Votre partenaire** serait-il intéressé à participer à notre étude? OUI NON

5) Avez-vous déjà accouché? OUI NON

Si oui, spécifier le # d'enfants _____

6) Combien de fois avez-vous été légalement séparée ou divorcée? _____

7) Avez-vous déjà été veuve? OUI NON

8) Avec combien de partenaires avez-vous cohabité ou avez-vous été mariée?
_____

9) Combien de relations amoureuses considérées "sérieuses" avez-vous eu dans votre vie? _____

10) Quel est le nombre total de partenaires avec qui vous avez eu des relations sexuelles (incluant les aventures d'un soir) _____

11) À quel âge avez-vous eu votre première relation sexuelle? _____ ans

12) Vous souvenez-vous de cette expérience comme étant quelque chose de douloureux? OUI NON

HISTOIRE GYNÉCOLOGIQUE

1) Laquelle des situations suivantes caractérise le mieux vos menstruations des 6 derniers mois?

a) J'ai des menstruations régulières
b) J'ai un cycle irrégulier
c) Mes menstruations sont irrégulières car j'approche la ménopause
d) Je n'ai pas de menstruations parce que je nourris mon bébé au sein
e) Je n'ai pas de menstruations parce que j'ai subi une hystérectomie partielle
f) Je n'ai pas de menstruations parce que j'ai subi une hystérectomie complète
g) Je n'ai pas de menstruations parce que j'ai déjà eu ma ménopause
h) Autre. Veuillez spécifier _____

2) **Si vous avez des menstruations,** évaluez sur l'échelle suivante l'intensité de la douleur que vous ressentez lors de vos menstruations.

_____

0 1 2 3 4 5 6 7 8 9 10

aucune douleur — douleur la plus intense

3) **Si vous avez déjà eu votre ménopause,** indiquez la date à laquelle vous avez eu vos dernières menstruations.

_____/_____
mois année

4) **Si vous avez déjà eu votre ménopause,** prenez-vous des hormones? OUI NON

Si oui, a) depuis quand? _____/_____
mois année

b) Quelle sorte d'hormones prenez-vous actuellement? _____

c) Quelle est la dose? _____

d) Avez-vous déjà pris d'autres types d'hormones? OUI NON

Si oui, indiquez i) quelle sorte _____
ii) quelle dose _____
iii) combien de temps_____

Si non, en avez-vous déjà pris? OUI NON

5) Si vous avez déjà pris des hormones et que vous avez arrêté d'en prendre, indiquez pourquoi.

_____

6) Avez-vous déjà pris la pilule? OUI NON

7) **Si oui**, à quel âge avez-vous commencé à la prendre ?_____ans

8) **Si oui**, indiquez le nombre total d'années et de mois de votre vie durant lesquels vous avez pris la pilule.

_____mois _____ années

9) Lequel des points suivants caractérise le mieux votre situation actuelle en termes de contraception? (encerclez tous les items qui s'appliquent)

a) Douche vaginale
b) Gelée ou mousse spermicide
c) Condoms
d) Diaphragme
e) Cape cervicale
f) L'éponge
g) Le stérilet
h) La pilule
i) Pilule du lendemain
j) Ligature des trompes
k) Hystérectomie
l) Mon partenaire a eu une vasectomie
m) Je suis infertile
n) Mon partenaire est infertile
o) Je n'ai plus de menstruations en raison de ma ménopause
p) Méthode du calendrier (s'abstenir pendant l'ovulation)
q) Coït interrompu
r) Pas de contraception mais je ne veut pas devenir enceinte
s) J'essaie de devenir enceinte
t) Je suis enceinte
u) Je nourris mon bébé au sein
v) Je n'ai pas de relations sexuelles
w) Pas de partenaires/pas de contraception
x) Autre. Veuillez spécifier

_____

_____

POUR LES FEMMES AYANT DÉJÀ ACCOUCHÉ (# 10, 11, 12)

10) Combien de césariennes avez-vous eu? _____

11) Combien d'accouchements avec épisiotomie avez-vous eu? _____

12) Combien d'accouchements avec déchirement du vagin avez-vous eu?_____

13) Combien de fausse-couches avez-vous eu? _____

14) Combien d'avortements avez-vous eu? _____

15) Combien d'infections vaginales (candida, etc.) avez-vous eu dans les derniers deux ans? _____

a) Quels traitements avez-vous utilisé?_____

b) Comment les infections ont-elles été diagnostiquées?
i) avis du médecin et cultures positives
ii) avis du médecin seulement
iii) auto-diagnostic

16) Avez-vous eu des infections vaginales à répétition dans le passé? OUI NON

17) Combien d'infections de la vessie ou urinaires (cystites) avez-vous eu dans les derniers deux ans? _____

a) Quels traitements avez-vous utilisé?_____

b) Comment les infections ont-elles été diagnostiquées?
i) avis du médecin et analyse d'urine positive
ii) avis du médecin seulement
iii) autre (veuillez spécifier) _____

18) Avez-vous eu des infections de la vessie ou urinaires (cystites) à répétition dans le passé? OUI NON

19) Combien de fois urinez-vous en une journée? _____

20) Avez-vous déjà souffert des MTS (maladies transmises sexuellement) suivantes? (Cochez si ça s'applique)

Chlamydia_____
Gardnerella vaginalis_____
Herpes génital_____
Condylomes _____
Gonorrhée_____
H.I.V_____
Siphyllis_____
Trichomoniasis _____
Autre_____Veuillez spécifier_____

21) Avez-vous déjà souffert d'une salpingite?
OUI, présentement
OUI, dans le passé
NON

22) Avez-vous déjà souffert d'endométriose?
OUI, présentement
OUI, dans le passé
NON

23) Avez-vous déjà subi les chirurgies génitales/gynécologiques suivantes? Si oui, quand?

Hystérectomie_____	Année_____
Laparoscopie_____	Année_____
Ovariectomie_____	Année_____
Ligatures des trompes_____	Année_____
Laser pour condyomes_____	Année_____
Autre_____	Année_____

HISTOIRE DE LA DOULEUR

1) Quand avez-vous commencé à ressentir de la douleur pendant les relations sexuelles?

_____mois_____année

2) Comment cela a-t-il commencé? (cochez tout ce qui s'applique)

a) avec ma première relation sexuelle
b) après des infections vaginales répétées
c) après avoir accouché
d) sans raison apparente
e) quant j'ai changé de partenaire
f) après des infections urinaires répétées
g) avec l'arrivée de ma ménopause
h) après une chirurgie gynécologique
i) après un stress important (e.g. conflit conjugal, problèmes financiers,etc.)
j) après un avortement
k) autre_____

3) Avez-vous toujours ressenti de la douleur pendant les relations sexuelles depuis la première fois que vous avez ressenti ce type de douleur?

a) oui
b) non, ça dépend du partenaire
c) non, quand j'ai arrêté de prendre la pilule, la douleur est disparue, puis est revenue
d) non, ça vient et ça part sans raison apparente
e) no, après avoir accouché, ça s'est arrêté temporairement et puis c'est revenu
f) non, après le traitement suivant _____, ça s'est arrêté et puis c'est revenu
g) non, autre_____

4) Avez-vous eu plus d'un partenaire depuis que la douleur a commencé? OUI NON

5) Combien de professionnels de la santé avez-vous consulté pour votre douleur?_____

6) Quels diagnostics et quels traitements vous ont-ils été donnés par les professionnels de la santé à qui vous avez parlé de votre douleur?

Veuillez dresser la liste de tous les diagnostics et médicaments/traitements dont vous vous souvenez ainsi que le nombre de fois que vous avez pris/subi le traitement prescrit.

Diagnostic	Traitement	Nombre de fois reçu
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

7) I) Avez-vous déjà essayé de traiter ou de soulager la douleur à l'aide des moyens suivants?

Encerclez le moyen ainsi que la méthode utilisée (ex.: changer de matelas)

II) Jusqu'à quel point cette méthode vous a-t-elle aidé, sur une échelle de 0 (pas du tout) à 10 (guérison complète)?

a) quelques changements mineurs
porter des sous–vêtements de coton_____
utiliser un savon doux ou aucun savon_____
bains spéciaux_____
changer de matelas_____
autre (veuillez spécifier)_____

_____

b) changements dans vos pratiques sexuelles
changer de position pour les relations sexuelles_____
demander à votre partenaire d'aller plus lentement_____
essayer d'augmenter l'excitation sexuelle en prolongeant les jeux préliminaires____
essayer d'augmenter l'excitation sexuelle en portant des sous–vêtements sexy_____
essayer d'augmenter l'excitation sexuelle en regarder des films érotiques_____
vous affirmer davantage sexuellement_____
changer de partenaire_____
autre (veuillez spécifier)_____

_____

c) utiliser différentes crèmes
un lubrifiant pour vous–même ou pour votre partenaire (ex.: K–Y, Crisco)_____
une crème hydratante (ex.: Prevex ou autre crème sans prescription)_____
une crème avec corticostéroïdes prescrite par un médecin_____
une gelée anesthésique (qui "gèle" la zone douloureuse, ex.: Xylocaïne)_____
une crème hormonale (ex.: crème Premarin)_____
une crème antifongique_____
autre (veuillez spécifier)_____

_____

d) médecine douce/alternative
prendre des vitamines (ex.: vitamine E)_____
remèdes homéopathiques (produits naturels, herbes, etc.)_____
alimentation/diète (ex.: réduire l'oxalate de calcium, le sucre, etc.)_____
physiothérapie_____
ostéopathie_____
acupuncture_____
massothérapie_____
autre (veuillez spécifier)_____

_____

e) psychothérapie
psychothérapie individuelle_____
thérapie de couple_____
thérapie sexuelle_____
hypnose_____
exercices de relaxation_____
exercices Kegel ou de dilatation_____
biofeedback_____
autre (veuillez spécifier)_____

_____

f) autres traitements médicaux
thérapie hormonale par voie orale (comprimés tels que Premarin/Provera)
antibiotiques
antifongiques
antiviraux
injections d'interféron
autre (veuillez spécifier) _____

_____

g) chirurgie
curetage
laser
vestibulectomie
autre (veuillez spécifier)_____

_____

h) autre (veuillez spécifier)_____ _____

8) Y a-t-il d'autres membres de votre famille qui souffrent ou qui ont souffert du même problème? OUI NON Non discuté
Si oui, quelle est leur relation avec vous?_____

9) Dans le passé, vous est-il déjà arrivé un incident comprenant de la douleur vulvaire?
OUI NON

Veuillez spécifier _____

(pour les femmes ayant présentement des relations sexuelles)

DOULEUR

1) Durant les derniers 6 mois, environ combien de fois par mois avez-vous essayé d'avoir des relations sexuelles? _____ **(Si réponse = 0, allez à la page 14)**

2) Durant les derniers 6 mois, avez-vous ressenti de la douleur ou un inconfort significatif avant, pendant ou après les relations sexuelles? OUI NON **Si non, allez à Q-4**

3) Pourquoi croyez-vous que vous ressentez de la douleur pendant les relations sexuelles? Quelle est votre théorie personnelle en ce qui concerne votre douleur?

_____
_____
_____
_____

4) Durant les derniers 6 mois, environ combien de fois par mois le pénis en érection de votre partenaire a-t-il pu pénétrer votre vagin (relation sexuelle réussie)?
_____fois par mois

5) Durant les derniers 6 mois, le pénis en érection de votre partenaire demeure en moyenne combien de temps dans votre vagin? _____minutes

6) Durant les derniers 6 mois environ, combien de fois par mois ressentez-vous de la douleur pendant les relations sexuelles? _____fois par mois

7) Lorsque vous avez de la douleur, est-elle toujours de la même intensité ou varie-t-elle?

OUI NON (varie)

8) **Si ça s'applique:** Avez-vous remarqué quelque chose de spécial à propos des fois où vous avez plus ou moins de douleur? Pouvez-vous identifier des circonstances particulièrement favorables ou défavorables? Veuillez cocher les points qui s'appliquent à votre cas ou spécifier les circonstances qui ne sont pas énumérées ci-dessous.

Cela dépend de... (cochez tous les points qui s'appliquent)

Jusqu'à quel point je suis fatiguée_____
Jusqu'à quel point je suis excitée_____
Jusqu'à quel point je suis lubrifiée_____
La durée des jeux préliminaires_____
La position que nous adoptons pour faire l'amour _____
L'endroit où nous nous trouvons____
Jusqu'à quel point je suis nerveuse ou anxieuse_____
Où je me trouve dans mon cycle menstruel_____
Le partenaire avec lequel je me trouve_____
Si je suis fâchée contre mon partenaire____

Si nous sommes seuls dans la maison_____
Le moment de la journée_____
Si j'ai consommé un breuvage alcoolisé_____
Si j'ai consommé des drogues_____
Le durée de temps écoulé depuis notre dernière relation sexuelle_____
La durée de notre relation sexuelle_____
Autre _____(veuillez spécifier)_____

9) Quand la douleur commence-t-elle habituellement?

a) avant que le pénis ne touche à l'entrée du vagin
b) quand le pénis commence à entrer dans le vagin
c) quand le pénis a complètement pénétré le vagin et qu'il y a du va-et-vient
e) moins d'1/2 heure après la fin de la relation sexuelle
f) plus d'1/2 heure après la fin de la relation sexuelle
g) autre (veuillez spécifier) _____

10) Une fois la douleur apparue, durant quelles étapes de la relation sexuelle la ressentez-vous?

a) seulement durant l'entrée du pénis
b) seulement durant le mouvement de va–et–vient du pénis
c) seulement pour un peu de temps après la sortie du pénis
d) durant l'entrée du pénis et après sa sortie
e) durant l'entrée du pénis et durant le mouvement de va-et-vient
f) durant le mouvement de va–et–vient du pénis et quelque temps après sa sortie
g) à l'entrée du pénis, durant son mouvement de va–et–vient et après sa sortie
h) ce n'est jamais pareil: il n'y a pas de "pattern"

S'il y a lieu, indiquez la durée de la douleur après le retrait du pénis

Durée: _____minutes _____heures _____jours

11) À quel endroit de la région génitale ressentez-vous habituellement la douleur lors des relations sexuelles? Pouvez-vous m'indiquer un endroit précis? **Si oui**, où? (Vous pouvez choisir plus d'un endroit) **(Montrez modèle et codez sur le diagramme)**

a) à l'entrée du vagin
b) partout sur la vulve
c) à l'intérieur du vagin
d) dans la région abdominale (utérus, etc.)

<u>vestibule</u>

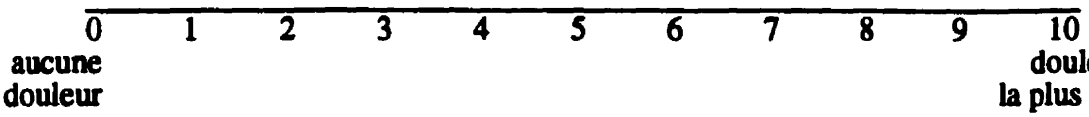
12

9-12 ___ ___ 12-3

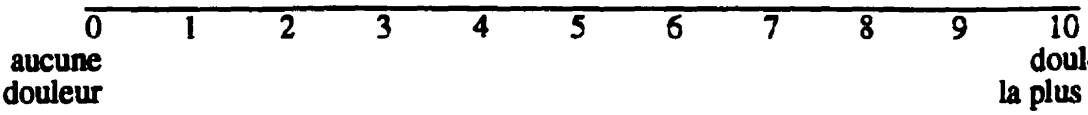
6-9 ___ ___ 3-6

6

12) Évaluez l'intensité moyenne de votre douleur à l'entrée et/ou à l'intérieur du vagin (derniers 6 mois) sur une échelle de 0 à 10



13) Évaluez l'intensité moyenne de votre douleur dans la région abdominale (derniers 6 mois) sur une échelle de 0 à 10



14) Durant les derniers 6 mois, avez-vous régulièrement ressenti de la douleur dans la région génitale lors des situations suivantes?

a) friction due à des vêtements serrés_____
b) quand vous urinez_____
c) à l'insertion d'un tampon_____
d) en enlevant un tampon_____
e) durant la masturbation (seule)_____
f) lorsque votre partenaire vous stimule manuellement_____
g) lorsque votre partenaire vous stimule oralement_____
h) en insérant un ou plusieurs doigts dans votre vagin_____
i) lors d'un examen gynécologique régulier_____
j) lors d'activité(s) sportive(s)_____
k) douleur sans raison apparente, non-liée à une activité spécifique_____
l) autre_____ veuillez spécifier_____

15) Souffrez-vous **régulièrement** des douleurs suivantes? Cochez tous les points qui s'appliquent.

Douleur au cou___
Douleur aux reins___
Maux de gorge___
Maux de dents___
Douleurs aux oreilles___
Autre_____Veuillez spécifier_____

(pour les femmes n'ayant pas de relations sexuelles)

DOULEUR

1) Combien de temps cela fait-il que vous n'avez pas eu de relations sexuelles?

_____ mois _____années

2) Quelle est la raison pour laquelle vous n'avez pas eu de relations sexuelles dans les derniers 6 mois?

a) Je n'ai pas de partenaire présentement
b) Ça fait trop mal
c) Je n'ai pas de désir sexuel
d) Mon partenaire a des problèmes d'érection
e) Mon partenaire n'a pas de désir sexuel
f) Mon partenaire a peur de me faire mal
g) Autre_____

3) Désirez-vous recommencer à avoir des relations sexuelles? OUI NON

4) Lors de vos relations sexuelles passées, avez-vous ressenti de la douleur ou un inconfort significatif avant, pendant ou après les relations sexuelles? OUI NON
Si non, passez à Q-6

5) Pourquoi croyez-vous que vous ressentez de la douleur pendant les relations sexuelles? Quelle est votre théorie personnelle en ce qui concerne votre douleur?

_____
_____
_____
_____

6) Dans le passé, environ combien de fois par mois essayiez-vous d'avoir des relations sexuelles? _____

7) Dans le passé, environ combien de fois par mois le pénis en érection de votre partenaire pouvait-il pénétrer votre vagin (relation sexuelle réussie)?
_____fois par mois

8) Dans le passé, le pénis en érection de votre partenaire demeurait en moyenne combien de temps dans votre vagin? _____minutes

9) Dans le passé, environ combien de fois par mois ressentiez-vous de la douleur pendant les relations sexuelles? _____fois par mois

10) Lorsque vous avez de la douleur, est-elle toujours de la même intensité ou varie-t-elle?

OUI NON (varie)

11) **Si ça s'applique:** Avez-vous remarqué quelque chose de spécial à propos des fois où vous aviez plus ou moins de douleur? Pouvez-vous identifier des circonstances particulièrement favorables ou défavorables? Veuillez cocher les points qui s'appliquent à votre cas ou spécifier les circonstances qui ne sont pas énumérées ci-dessous.

Cela dépendait de... (cochez tous les points qui s'appliquent)

Jusqu'à quel point j'étais fatiguée_____
Jusqu'à quel point j'étais excitée_____
Jusqu'à quel point j'étais lubrifiée_____
La durée des jeux préliminaires_____
La position que nous adoptions pour faire l'amour _____
L'endroit où nous nous trouvions____
Jusqu'à quel point j'étais nerveuse ou anxieuse_____
Où je me trouvais dans mon cycle menstruel_____
Le partenaire avec lequel je me trouvais_____
Si j'étais fâchée contre mon partenaire_____
Si nous étions seuls dans la maison_____
Le moment de la journée_____
Si j'avais consommé un breuvage alcoolisé_____
Si j'avais consommé des drogues_____
Le durée de temps écoulé depuis notre dernière relation sexuelle_____
La durée de notre relation sexuelle_____
Autre _____(veuillez spécifier)_____

12) Quand la douleur commençait-t-elle habituellement?

a) avant que le pénis ne touche à l'entrée du vagin
b) quand le pénis commençait à entrer dans le vagin
c) quand le pénis avait complètement pénétré le vagin et qu'il y avait du va-et-vient
e) moins d'1/2 heure après la fin de la relation sexuelle
f) plus d'1/2 heure après la fin de la relation sexuelle
g) autre (veuillez spécifier) _____

13) Une fois la douleur apparue, durant quelles étapes de la relation sexuelle la ressentiez-vous?

a) seulement durant l'entrée du pénis
b) seulement durant le mouvement de va–et–vient du pénis
c) seulement pour un peu de temps après la sortie du pénis
d) durant l'entrée du pénis et après sa sortie
e) durant l'entrée du pénis et durant le mouvement de va-et-vient
f) durant le mouvement de va–et–vient du pénis et quelque temps après sa sortie
g) à l'entrée du pénis, durant son mouvement de va–et–vient et après sa sortie
h) ce n'est jamais pareil: il n'y a pas de "pattern"

S'il y a lieu, indiquez la durée de la douleur après le retrait du pénis

Durée: _____minutes _____heures _____jours

14) À quel endroit de la région génitale ressentiez-vous habituellement la douleur lors des relations sexuelles? Pouvez-vous m'indiquer un endroit précis? **Si oui**, où? (Vous pouvez choisir plus d'un endroit) **(Montrez modèle et codez sur le diagramme)**

a) à l'entrée du vagin
b) partout sur la vulve
c) à l'intérieur du vagin
d) dans la région abdominale (utérus, etc.)

vestibule

12

9-12 ___ ___ 12-3

6-9 ___ ___ 3-6

6

15) Évaluez l'intensité moyenne de votre douleur à l'intérieur et/ou à l'entrée du vagin sur une échelle de 0 à 10

0 1 2 3 4 5 6 7 8 9 10
aucune douleur — douleur la plus intense

16) Évaluez l'intensité moyenne de votre douleur dans la région abdominale sur une échelle de 0 à 10

0 1 2 3 4 5 6 7 8 9 10
aucune douleur — douleur la plus intense

17) Avez-vous déjà régulièrement ressenti de la douleur dans la région génitale lors des situations suivantes?

a) friction due à des vêtements serrés_____
b) en urinant_____ en urinant après une relation sexuelle _____
c) à l'insertion d'un tampon_____
d) en enlevant un tampon_____
e) durant la masturbation (seule)_____
f) lorsque votre partenaire vous stimule manuellement_____
g) lorsque votre partenaire vous stimule oralement_____
h) en insérant un ou plusieurs doigts dans votre vagin_____
i) lors d'un examen gynécologique régulier_____
j) lors d'activité(s) sportive(s)_____
k) douleur sans raison apparente, non-liée à une activité spécifique_____
l) autre_____ veuillez spécifier_____

18) Souffrez-vous **régulièrement** des douleurs suivantes? Cochez tous les points qui s'appliquent.

Douleur au cou___
Douleur aux reins___
Maux de gorge___
Maux de dents___
Douleurs aux oreilles___
Autre_____Veuillez spécifier_____

Appendix 7 - Post-Treatment and 6-month Follow-Up Structured Interview Randomized Treatment Outcome Study

STRUCTURED INTERVIEW

WOMEN

POST-TREATMENT

AND

6-MONTH FOLLOW-UP

circle one or the other

Subject Number _____

Referred from _____

Interviewer _____

Date of interview _____

RELATIONSHIP HISTORY

1) Is your current relationship status the same as it was at the time of the first interview? YES NO If YES, go to the following section.

For women who's relationship status is different than at the first interview:

2) Which of the following best describes your current situation?

a) no regular partner at the moment
b) dating one partner regularly
c) living with a partner
d) married

3) How long have you been in the situation you circled above?

_____ years _____ months

4) If you have a partner, please state how old he is. _____ years

5) Would your partner be willing to participate in this study? YES NO

GYNECOLOGICAL HISTORY

1) Please the average intensity of the pain you experienced during your menstrual periods in the last 3 (or 6) months.

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

2) Which of the following best describes your situation at the moment in terms of contraception? (please circle as many as apply)

a) Douche
b) Spermicide jelly or foam
c) Condoms
d) Diaphragm
e) Cervical cap
f) Sponge
g) IUD
h) The pill
i) Morning-after pill
j) Tubal ligation (tubes tied)
k) Hysterectomy
l) Partner has vasectomy
m) You are infertile
n) Partner is infertile
o) You no longer have periods due to menopause
p) Rhythm method (abstain when ovulating)
q) Partner exits before ejaculating
r) No contraceptive measures taken but do not want to get pregnant
s) Trying to get pregnant
t) You are pregnant
u) You are breast-feeding
v) Do not engage in intercourse at all
w) No partner/no measures
x) Other. Please specify

_____

_____

3) How many yeast or other vaginal infections have you had in the last 3 (or 6) months?

_____

a) What treatments did you use? _____

b) How were they diagnosed? i) clinical plus positive culture
ii) clinical only
iii) self-diagnosed

4) How many bladder/urinary infections (cystitis) have you had in the last 3 (or 6) months? _____

a) What treatments did you use? _____

b) How were they diagnosed? i) clinical plus urinalysis
ii) clinical only
iii) other (please specify) _____

5) In the last 3 (or 6) months, approximately how often did you urinate in one day ?

_____

(all women presently having intercourse)

PAIN

1) Over the past 3 (or 6) months approximately how many times have you **attempted** to have intercourse per month? _____ (IF ANSWER = 0 proceed to following section)

2) In the past 3 (or 6) months approximately how many times per month has your partner's erect penis been able to enter your vagina (succeeded in having intercourse)? _____ times per month.

3) In the past 3 (or 6) months, what was the average length of time that your partner's erect penis was in your vagina ? _____ minutes

4) In the past 3 (or 6) months, have you ever experienced pain or significant discomfort before, during or after intercourse? YES NO If NO, skip to question 8.

5) In the last 3 (or 6) months approximately how many times per month did you experience pain due to intercourse? _____ times per month.

6) How long did the pain typically last ?

a) during penile entry only
b) during the penile thrusting only
c) only for a period after penile exit
d) during penile entry and after penile exit
e) during penile entry and during penile thrusting
f) during penile thrusting and for some time after penile exit
g) during penile entry, during penile thrusting and after penile exit
h) it is never the same: there is no typical pattern

If it lasts after penile exit, please state for how long after, the pain is felt

Time: _____ minutes _____ hours _____ days

7) Where did you typically feel the pain during intercourse? Is there a specific spot you can show me? If yes, where ? (You may select more than one)

a) at the vaginal opening
b) everywhere on the vulva
c) inside the vagina
d) in the pelvic or abdominal region

8) Rate the average intensity of the pain at the entry and/or lower part of the vagina (past 3 or 6 months) on a scale of 0 to 10:

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

9) Rate the average intensity of the pain in the pelvic or abdominal region (past 3 or 6 months) on a scale of 0 to 10:

0	1	2	3	4	5	6	7	8	9	10
no pain										worst pain ever

10) In the past 3 (or 6) months have you regularly experienced pain in your genital area in any of the following situations?

a) Friction with clothing _____
b) Urinating in general _____ Urinating after intercourse _____
c) Inserting a tampon _____
d) Removing a tampon _____
e) Masturbating alone _____
f) Partner stimulating you manually _____
g) Partner stimulating you orally _____
h) Finger insertion _____
i) Standard gynecological examination _____
j) Sporting activity (please specify) _____
k) Pain not related to any specific activity _____
l) Other _____ please specify _____

11) In the past 3 (or 6) months have you attempted to treat or alleviate the pain in any other way than the treatment you received in the study? YES NO

If YES, name treatment (s) used: _____

12) Up to what point do you feel your pain has improved following the treatment you received in the study?

a) Complete cure (no more pain)
b) Great improvement
c) Average improvement
d) Little improvement
e) No improvement
f) Worse

13) Can you think of anything else, aside from the treatment you received in the study, that might have contributed to improve or eliminate your pain?

_____
_____
_____

14) On a scale of 0 to 10, please rate your overall satisfaction with the treatment you received:

0	1	2	3	4	5	6	7	8	9	10
completely dissatisfied										completely satisfied

(women not having intercourse now)

PAIN

1) How long has it been since the last time you had intercourse?

_____ months _____ years

2) What is the reason you have not had intercourse in the past 3 (or 6) months?

a) I have no partner at the moment
b) it hurts too much
c) I have no desire
d) my partner has an erection problem
e) my partner has no desire
f) my partner is concerned about hurting me
g) other _____

3) Do you want to resume intercourse? YES NO

4) Rate the average intensity of the pain at the entry and/or lower part of the vagina (past 3 or 6 months) on this scale of 0 to 10:

0	1	2	3	4	5	6	7	8	9	10
no pain									pain ever	worst

5) Rate the average intensity of the pain in the pelvic or abdominal region (past 3 or 6 months) on this scale of 0 to 10:

0	1	2	3	4	5	6	7	8	9	10
no pain									pain ever	worst

6) In the last 3 (or 6) months, have you experienced pain in your genital area in any of the following situations?

a) Friction with clothing _____
b) Urinating in general _____ Urinating after intercourse _____
c) Inserting a tampon _____
d) Removing a tampon _____
e) Masturbating alone _____
f) Partner stimulating you manually _____
g) Partner stimulating you orally _____
h) Finger insertion _____
i) Standard gynecological examination _____
j) Sporting activity (please specify) _____
k) Pain not related to any specific activity _____
l) Other _____ please specify _____

7) In the past 3 (or 6) months have you attempted to treat or alleviate the pain in any other way than the treatment you received in the study? YES NO

If YES, name treatment (s) used: _____

8) Up to what point do you feel your pain has improved following the treatment you received in the study?

a) Complete cure (no more pain)
b) Great improvement
c) Average improvement
d) Little improvement
e) No improvement
f) Worse

9) Can you think of anything else, aside from the treatment you received in the study, that might have contributed to improve or eliminate your pain?

_____
_____
_____

10) On a scale of 0 to 10, please rate your overall satisfaction with the treatment you received:

_____

0	1	2	3	4	5	6	7	8	9	10
completely dissatisfied										completely satisfied

ENTREVUE DIRIGÉE

FEMMES

POST-TRAITEMENT

ET

SUIVI DE 6 MOIS

encerclez l'un ou l'autre

Numéro du sujet _____

Référée par _____

Intervieweur _____

Date de l'entrevue _____

HISTOIRE RELATIONNELLE

1) Est-ce que votre statut civil est le même que lors de la première entrevue?
OUI NON Si OUI, passez à la section suivante.

Pour les femmes dont le statut civil est différent de celui de la première entrevue:

2) Lequel des points suivants décrit le mieux votre statut civil actuel?

a) célibataire non engagée dans une relation
b) célibataire avec un partenaire régulier
c) en union de fait
d) mariée depuis

3) Depuis combien de temps êtes-vous dans la situation encerclée ci-dessus?

_____années _____mois

4) **Si vous avez un partnenaire**, quel âge a-t-il? _____ ans

5) **Votre partenaire** serait-il intéressé à participer à notre étude? OUI NON

HISTOIRE GYNÉCOLOGIQUE

1) Evaluez sur l'échelle suivante l'intensité de la douleur que vous avez ressenti lors de vos menstruations dans les derniers 3 (ou 6) mois:

0	1	2	3	4	5	6	7	8	9	10
aucune douleur										douleur la plus intense

2) Lequel des points suivants caractérise le mieux votre situation actuelle en termes de contraception? (encerclez tous les items qui s'appliquent)

a) Douche vaginale
b) Gelée ou mousse spermicide
c) Condoms
d) Diaphragme
e) Cape cervicale
f) L'éponge
g) Le stérilet
h) La pilule
i) Pilule du lendemain
j) Ligature des trompes
k) Hystérectomie
l) Mon partenaire a eu une vasectomie
m) Je suis infertile
n) Mon partenaire est infertile
o) Je n'ai plus de menstruations en raison de ma ménopause
p) Méthode du calendrier (s'abstenir pendant l'ovulation)
q) Coït interrompu
r) Pas de contraception mais je ne veut pas devenir enceinte
s) J'essaie de devenir enceinte
t) Je suis enceinte
u) Je nourris mon bébé au sein
v) Je n'ai pas de relations sexuelles
w) Pas de partenaires/pas de contraception
x) Autre. Veuillez spécifier

_____

_____

3) Combien d'infections vaginales (candida, etc.) avez-vous eu dans les derniers 3 (ou 6) mois? _____

a) Quels traitements avez-vous utilisé?_____

b) Comment les infections ont-elles été diagnostiquées?
i) avis du médecin et cultures positives
ii) avis du médecin seulement
iii) auto-diagnostic

4) Combien d'infections de la vessie ou urinaires (cystites) avez-vous eu dans les derniers 3 (ou 6) mois? _____

a) Quels traitements avez-vous utilisé?_____

b) Comment les infections ont-elles été diagnostiquées?
i) avis du médecin et analyse d'urine positive
ii) avis du médecin seulement
iii) autre (veuillez spécifier) _____

5) Dans les derniers 3 (ou 6) mois, environ combien de fois uriniez-vous en une journée?

_____

(pour les femmes ayant présentement des relations sexuelles)

DOULEUR

1) Durant les derniers 3 (ou 6) mois, environ combien de fois par mois avez-vous essayé d'avoir des relations sexuelles? _____ (SI REPONSE = 0, passez à la section suivante)

2) Durant les derniers 3 (ou 6) mois, environ combien de fois par mois le pénis en érection de votre partenaire a-t-il pu pénétrer votre vagin (relation sexuelle réussie)? _____fois par mois

3) Durant les derniers 3 (ou 6) mois, le pénis en érection de votre partenaire demeurait en moyenne combien de temps dans votre vagin? _____minutes

4) Durant les derniers 3 (ou 6) mois, avez-vous ressenti de la douleur ou un inconfort significatif avant, pendant ou après les relations sexuelles? OUI NON Si NON, allez à la question 8.

5) Durant les derniers 3 (ou 6) mois, environ combien de fois par mois ressentiez-vous de la douleur pendant les relations sexuelles? _____fois par mois

6) Une fois la douleur apparue, durant quelles étapes de la relation sexuelle la ressentiez-vous?

   a) seulement durant l'entrée du pénis
   b) seulement durant le mouvement de va–et–vient du pénis
   c) seulement pour un peu de temps après la sortie du pénis
   d) durant l'entrée du pénis et après sa sortie
   e) durant l'entrée du pénis et durant le mouvement de va-et-vient
   f) durant le mouvement de va–et–vient du pénis et quelque temps après sa sortie
   g) à l'entrée du pénis, durant son mouvement de va–et–vient et après sa sortie
   h) ce n'est jamais pareil: il n'y a pas de "pattern"

   S'il y a lieu, indiquez la durée de la douleur après le retrait du pénis

   Durée: _____minutes _____heures _____jours

7) À quel endroit de la région génitale ressentiez-vous habituellement la douleur lors des relations sexuelles? Pouvez-vous m'indiquer un endroit précis? Si oui, où? (Vous pouvez choisir plus d'un endroit)

   a) à l'entrée du vagin
   b) partout sur la vulve
   c) à l'intérieur du vagin
   d) dans la région abdominale (utérus, etc.)

8) Évaluez l'intensité moyenne de votre douleur à l'entrée et/ou à l'intérieur du vagin (derniers 3 ou 6 mois) sur une échelle de 0 à 10:

0	1	2	3	4	5	6	7	8	9	10
aucune douleur										douleur la plus intense

9) Évaluez l'intensité moyenne de votre douleur dans la région abdominale (derniers 3 ou 6 mois) sur une échelle de 0 à 10:

0	1	2	3	4	5	6	7	8	9	10
aucune douleur										douleur la plus intense

10) Durant les derniers 3 (ou 6) mois, avez-vous régulièrement ressenti de la douleur dans la région génitale lors des situations suivantes?

a) friction due à des vêtements serrés_____
b) quand vous urinez_____ en urinant après une relation sexuelle _____
c) à l'insertion d'un tampon_____
d) en enlevant un tampon_____
e) durant la masturbation (seule)_____
f) lorsque votre partenaire vous stimule manuellement_____
g) lorsque votre partenaire vous stimule oralement_____
h) en insérant un ou plusieurs doigts dans votre vagin_____
i) lors d'un examen gynécologique régulier_____
j) lors d'activité(s) sportive(s)_____
k) douleur sans raison apparente, non-liée à une activité spécifique_____
l) autre_____ veuillez spécifier_____

11) Dans les derniers 3 (ou 6) mois, avez-vous essayé de traiter ou d'alléger la douleur de d'autres façons que le traitement que vous avez reçu dans l'étude? OUI NON

Si OUI, nommez le(s) traitement(s) utilisé(s): _____

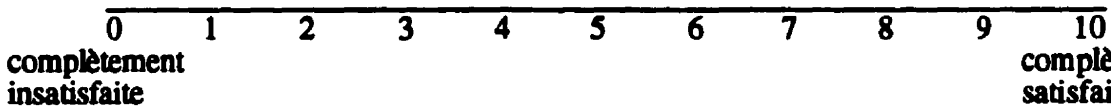
12) Jusqu'à quel point croyez-vous que votre douleur s'est améliorée suite au traitement que vous avez reçu dans l'étude?

a) Amélioration complète (plus aucune douleur)
b) Grande amélioration
c) Amélioration moyenne
d) Peu d'amélioration
e) Pas d'amélioration
f) Pire

13) Mis à part le traitement que vous avez reçu dans l'étude, pensez-vous à autre chose qui aurait pu contribuer à améliorer ou à éliminer votre douleur?

_____
_____
_____

14) Sur une échelle de 0 à 10, évaluez votre satisfaction générale vis-à-vis le traitement que vous avez reçu dans l'étude:



(pour les femmes n'ayant pas de relations sexuelles)

DOULEUR

1) Combien de temps cela fait-il que vous n'avez pas eu de relations sexuelles?

_____ mois _____années

2) Quelle est la raison pour laquelle vous n'avez pas eu de relations sexuelles dans les derniers 3 (ou 6) mois?

a) Je n'ai pas de partenaire présentement
b) Ça fait trop mal
c) Je n'ai pas de désir sexuel
d) Mon partenaire a des problèmes d'érection
e) Mon partenaire n'a pas de désir sexuel
f) Mon partenaire a peur de me faire mal
g) Autre_____

3) Désirez-vous recommencer à avoir des relations sexuelles? OUI NON

4) Évaluez l'intensité moyenne de votre douleur à l'intérieur et/ou à l'entrée du vagin (derniers 3 ou 6 mois) sur une échelle de 0 à 10:

0 1 2 3 4 5 6 7 8 9 10
aucune douleur — douleur la plus intense

5) Évaluez l'intensité moyenne de votre douleur dans la région abdominale (derniers 3 ou 6 mois) sur une échelle de 0 à 10:

0 1 2 3 4 5 6 7 8 9 10
aucune douleur — douleur la plus intense

6) Dans les derniers 3 (ou 6) mois, avez-vous déjà régulièrement ressenti de la douleur dans la région génitale lors des situations suivantes?

a) friction due à des vêtements serrés_____
b) en urinant_____ en urinant après une relation sexuelle _____
c) à l'insertion d'un tampon_____
d) en enlevant un tampon_____
e) durant la masturbation (seule)_____
f) lorsque votre partenaire vous stimule manuellement_____
g) lorsque votre partenaire vous stimule oralement_____
h) en insérant un ou plusieurs doigts dans votre vagin_____
i) lors d'un examen gynécologique régulier_____
j) lors d'activité(s) sportive(s)_____
k) douleur sans raison apparente, non-liée à une activité spécifique_____
l) autre_____ veuillez spécifier_____

7) Dans les derniers 3 (ou 6) mois, avez-vous essayé de traiter ou d'alléger la douleur de d'autres façons que le traitement que vous avez reçu dans l'étude? OUI NON

Si OUI, nommez le(s) traitement(s) utilisé(s): _____

8) Jusqu'à quel point croyez-vous que votre douleur s'est améliorée suite au traitement que vous avez reçu dans l'étude?

a) Amélioration complète (plus aucune douleur)
b) Grande amélioration
c) Amélioration moyenne
d) Peu d'amélioration
e) Pas d'amélioration
f) Pire

9) Mis à part le traitement que vous avez reçu dans l'étude, pensez-vous à autre chose qui aurait pu contribuer à améliorer ou à éliminer votre douleur?

_____
_____
_____

10) Sur une échelle de 0 à 10, évaluez votre satisfaction générale vis-à-vis le traitement que vous avez reçu dans l'étude:

_____

0 1 2 3 4 5 6 7 8 9 10

complètement insatisfaite — complètement satisfaite

Appendix 8 - McGill-Melzack Pain Questionnaire

Randomized Treatment Outcome Study

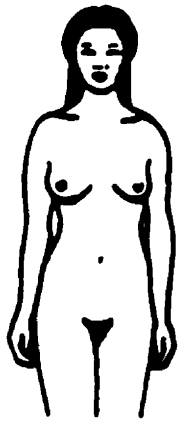
McGill · Melzack Pain Questionnaire

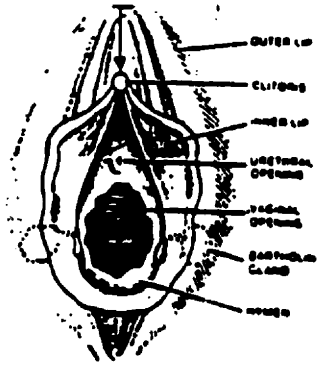
Patient's Name _____ Date _____

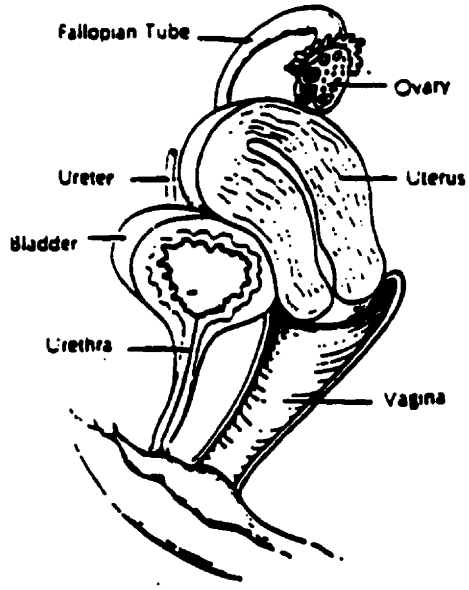
PRI: S _____ A _____ E _____ M(S) _____ M(AE) _____ M(T) _____ PRI(T) _____
(1-10) (11-15) (16) (17-19) (20) (17-20) (1-20)

1 FLICKERING	11 TIRING	
QUIVERING	EXHAUSTING	
PULSING	12 SICKENING	
THROBBING	SUFFOCATING	
BEATING	13 FEARFUL	
POUNDING	FRIGHTFUL	
2 JUMPING	TERRIFYING	
FLASHING	14 PUNISHING	
SHOOTING	GRUELLING	
3 PRICKING	CRUEL	
BORING	VICIOUS	
DRILLING	KILLING	
STABBING	15 WRETCHED	
LANCINATING	BLINDING	
4 SHARP	16 ANNOYING	
CUTTING	TROUBLESOME	
LACERATING	MISERABLE	
5 PINCHING	INTENSE	
PRESSING	UNBEARABLE	
GNAWING	17 SPREADING	
CRAMPING	RADIATING	
CRUSHING	PENETRATING	
6 TUGGING	PIERCING	
PULLING	18 TIGHT	
WRENCHING	NUMB	
7 HOT	DRAWING	
BURNING	SQUEEZING	
SCALDING	TEARING	
SEARING	19 COOL	
8 TINGLING	COLD	
ITCHY	FREEZING	
SMARTING	20 NAGGING	
STINGING	NAUSEATING	
9 DULL	AGONIZING	
SORE	DREADFUL	
HURTING	TORTURING	
ACHING	PPI	
HEAVY	0 No pain	
10 TENDER	1 MILD	
TAUT	2 DISCOMFORTING	
RASPING	3 DISTRESSING	
SPLITTING	4 HORRIBLE	
	5 EXCRUCIATING	

PPI _____ COMMENTS:







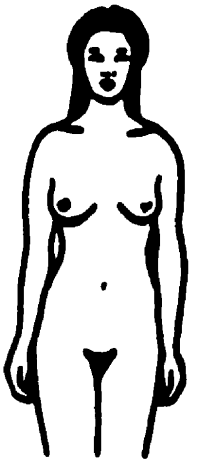
Questionnaire Melzack sur la douleur (McGill)

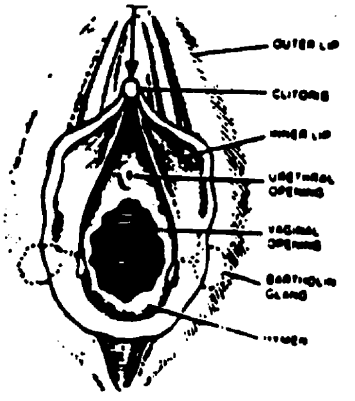
Nom du patient _____ Date _____

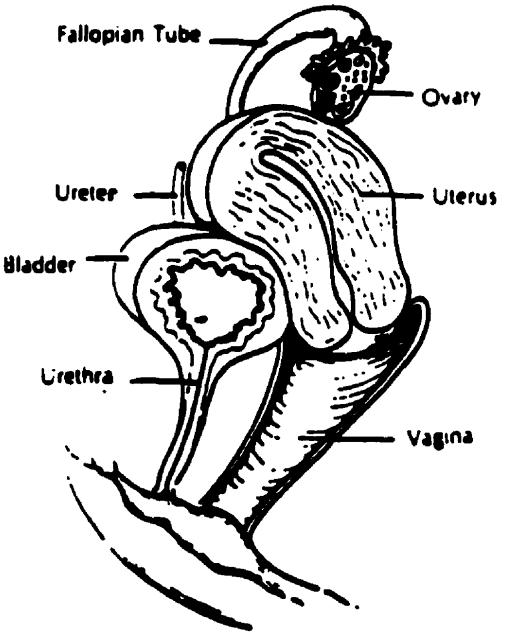
PRI S _____ (1-10) A _____ (11-15) E _____ (16) M(S) _____ (17-19) M(AE) _____ (20) M(T) _____ (17-20) PRI(T) _____ (1-20)

1 Qui tremblotte Qui tremble Qui palpite Qui bat Qui élance Qui martèle	12. Écœurante Étouffante	
2. Par secousse Brusque Fulgurante	13. Épeurante Effrayante Terrifiante	
3 Qui pique Qui perce Qui pénètre Qui poignarde	14. Violente Éreintante Cruelle Tuante Torturante	
4. Vive Aiguë Déchirante	15. Déprimante Aveuglante	
5. Qui pince Qui presse Qui ronge Qui crampe Qui écrase	16. Agaçante Exaspérante Intense Horrible Intolérable	
6. Qui tiraille Qui tire Qui tord	17. Qui s'étend Qui rayonne Qui rentre Qui transperce	
7 Chaude Brûlante Bouillante Comme marqué au fer rouge	18. Raide Engourdie Tendue Qui serre Qui arrache	
8. Qui fourmille Qui démange Cuisante Cinglante	19. Fraîche Froide Glacée	
9. Sourde Douloureuse Drue Pénible Poignante	20. Énervante Dégoûtante Épouvantable Atroce Agonisante	
10. Sensible Crispée Qui écorche Qui fend		0 Pas de douleur 1 Faible 2 Inconfortable 3 Forte 4 Sévère 5 Insupportable
11 Fatiguante Épuisante		

PPI _____ Commentaires:







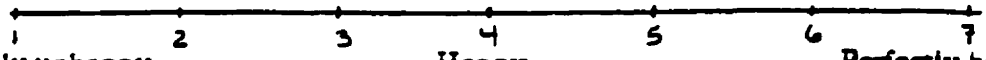
Appendix 9 - Locke-Wallace Marital Adjustment Scale

Randomized Treatment Outcome Study

Name:_____ Date:_____

RELATIONSHIP ADJUSTMENT SCALE

1. Check the point on the scale below which best describes the degree of happiness, everything considered, of your present marriage/relationship. The middle point, "HAPPY", represents the degree of happiness which most people get from their marriage/relationship, and the scale gradually ranges on one side to those few who are very unhappy in their marriage/relationship, and on the other,to those few who experience extreme joy or felicity in marriage/relationship.



Totally unhappy Happy Perfectly happy

State the approximate extent of agreement or disagreement between you and your mate on the following items. Please check the one most appropriate column for each item.

	Always Agree	Almost Always Agree	Occa-sionally Disagree	Fre-quently Disagree	Almost always Disagree	always Disagree
2. Handling family finances						
3. Matters of recreation						
4. Demonstration of affection						
5. Friends						
6. Sex relations						
7. Conventionality (right good, or proper conduct)						
8. Philosophy of life						
9. Ways of dealing with partner's parents						

10. When disagreements arise, they usually result in:

Man giving in_____Woman giving in_____Agreement by mutual give and take_____

11. Do you and your mate engage in outside interests together?

All of them_____ Some of them _____ Very few of them _____ None of them_____

12. In leisure time do you generally prefer: To be "on the go"? _____to stay at home?_____
Does your mate generally prefer: To be "on the go"? _____to stay at home?_____

13. Do you ever wish you had not married/moved in with your partner?

Frequently _____ Occasionally _____ Rarely _____ Never _____

14. If you had your life to live over, do you think you would:

Marry/live with the same person? ____ Marry/live with a different person? ____
Not marry at all?_____

15. Do you confide in your mate?

Almost never _____ Rarely _____ In most things _____ In everything _____

Nom: _____ Date: _____

ENQUETE MARITALE LOCKE-WALLACE

1. Veuillez cocher sur l'échelle ci-dessous le point qui décrit le mieux le degré de bonheur qui existe dans votre mariage actuel. Le point central, 'HEUREUX', représente le degré de bonheur que la plupart des gens éprouvent au cours de leur union maritale. L'échelle s'étend graduellement d'une part vers le petit nombre de personnes dont le mariage est très malheureux et, d'autre part, vers le petit nombre qui vivent une expérience maritale de bonheur absolu.

Très malheureux — Heureux — Parfaitement heureux

Veuillez indiquer pour chaque point suivant le degré approximatif d'accord ou de désaccord entre vous et votre conjoint. Veuillez donner une seule réponse appropriée pour chaque item.

	Toujours d'accord	Presque toujours d'accord	Désaccord occa-sionnel	Désaccord fréquent	Presque toujours en dé-	Toujours en dé-saccord
2. Administration du budget familial						
3. Récréation						
4. Témoignages d'affection						
5. Amis						
6. Relations sexuelles						
7. Usages conventionnels (conformité aux exi-gences de la société)						
8. Philosophie de la vie						
9. Façon d'agir avec la belle-famille						

10. Lorsqu'il y a désaccord, il en résulte habituellement:

que l'époux cède _____ que l'épouse cède_____ qu'il y accord par concessions mutuelles_____

11. Est-ce que vous et votre conjoint prenez part ensemble à des activités à l'extérieur?

Toutes — Quelques-unes — Très peu — Aucune —

12. Pendant vos heures de loisirs, vous préférez habituellement _____sortir _____rester à la maison. Votre conjoint préfère habituellement_____sortir _____rester à la maison

13. Avez-vous déjà souhaité ne pas être marié?

Fréquemment _____ de temps en temps _____ rarement _____ jamais_____

14. Si vous aviez le choix de refaire votre vie, que feriez-vous?

_____Je marierais la même personne. _____Je marierais quelqu'un d'autre_____
_____Je ne me marierais pas.

15. Vous vous confiez à votre conjoint:

presque jamais_____ rarement _____ le plupart du temps _____ toujours_____

Appendix 10 - Brief Symptom Inventory

Randomized Treatment Outcome Study

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Circle only one number for each problem and do not skip any items. If you change your mind, erase your first mark carefully. Read the example below before beginning, and if you have any questions please ask about them.

SEX
MALE ○
FEMALE ○

NAME: _____
LOCATION: _____
EDUCATION: _____
MARITAL STATUS MAR ___SEP ___DIV ___WID ___SING ___

DATE (MO | DAY | YEAR)
ID. NUMBER
AGE

VISIT NUMBER: _____

EXAMPLE HOW MUCH WERE YOU DISTRESSED BY:	NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1. Bodyaches	0	1	2	(3)	4

HOW MUCH WERE YOU DISTRESSED BY:		NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1. Nervousness or shakiness inside	1	0	1	2	3	4
2. Faintness or dizziness	2	0	1	2	3	4
3. The idea that someone else can control your thoughts	3	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	4	0	1	2	3	4
5. Trouble remembering things	5	0	1	2	3	4
6. Feeling easily annoyed or irritated	6	0	1	2	3	4
7. Pains in heart or chest	7	0	1	2	3	4
8. Feeling afraid in open spaces or on the streets	8	0	1	2	3	4
9. Thoughts of ending your life	9	0	1	2	3	4
10. Feeling that most people cannot be trusted	10	0	1	2	3	4
11. Poor appetite	11	0	1	2	3	4
12. Suddenly scared for no reason	12	0	1	2	3	4
13. Temper outbursts that you could not control	13	0	1	2	3	4
14. Feeling lonely even when you are with people	14	0	1	2	3	4
15. Feeling blocked in getting things done	15	0	1	2	3	4
16. Feeling lonely	16	0	1	2	3	4
17. Feeling blue	17	0	1	2	3	4
18. Feeling no interest in things	18	0	1	2	3	4
19. Feeling fearful	19	0	1	2	3	4
20. Your feelings being easily hurt	20	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	21	0	1	2	3	4
22. Feeling inferior to others	22	0	1	2	3	4
23. Nausea or upset stomach	23	0	1	2	3	4
24. Feeling that you are watched or talked about by others	24	0	1	2	3	4
25. Trouble falling asleep	25	0	1	2	3	4
26. Having to check and double check what you do	26	0	1	2	3	4
27. Difficulty making decisions	27	0	1	2	3	4
28. Feeling afraid to travel on buses, subways, or trains	28	0	1	2	3	4
29. Trouble getting your breath	29	0	1	2	3	4
30. Hot or cold spells	30	0	1	2	3	4
31. Having to avoid certain things, places, or activities because they frighten you	31	0	1	2	3	4
32. Your mind going blank	32	0	1	2	3	4
33. Numbness or tingling in parts of your body	33	0	1	2	3	4
34. The idea that you should be punished for your sins	34	0	1	2	3	4
35. Feeling hopeless about the future	35	0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY		NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure, or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds, such as shopping or at a movie	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4

Nom : _____ Date : _____

Voici une liste de problèmes dont se plaignent parfois les gens. Lisez attentivement chaque énoncé et encerclez le chiffre qui décrit le mieux COMBIEN VOUS AVEZ ÉTÉ INCOMMODÉ(E) PAR CE PROBLÈME DURANT LES SEPT (7) DERNIERS JOURS, INCLUANT AUJOURD'HUI ?

0 = Pas du tout
1 = Un peu
2 = Passablement
3 = Beaucoup
4 = Excessivement

1.	Nervosité ou impressions de tremblements intérieurs	0 1 2 3 4
2.	Faiblesses ou étourdissements	0 1 2 3 4
3.	L'idée que quelqu'un peut contrôler vos pensées	0 1 2 3 4
4.	L'impression que d'autres sont responsables de la plupart de vos problèmes	0 1 2 3 4
5.	Difficulté à vous rappeler certaines choses	0 1 2 3 4
6.	Facilement irritée et contrariée	0 1 2 3 4
7.	Douleurs à la poitrine ou cardiaques	0 1 2 3 4
8.	Peur dans des espaces ouverts ou sur la rue	0 1 2 3 4
9.	Des pensées de vous enlever la vie	0 1 2 3 4
10.	Le sentiment que vous ne pouvez pas avoir confiance en personne	0 1 2 3 4
11.	Manque d'appétit	0 1 2 3 4
12.	Soudainement effrayé(e) sans raison	0 1 2 3 4
13.	Crises de colère incontrôlables	0 1 2 3 4
14.	Sentiment d'être seul(e) même avec d'autres personnes	0 1 2 3 4
15.	Blocage devant une tâche à accomplir	0 1 2 3 4
16.	Vous sentir seul(e)	0 1 2 3 4
17.	Vous sentir triste, nostalgique	0 1 2 3 4
18.	Absence d'intérêt	0 1 2 3 4
19.	Avoir peur	0 1 2 3 4
20.	Vous sentir facilement blessé(e) ou froissé(e)	0 1 2 3 4
21.	Sentir que les gens ne sont pas aimables ou ne vous aiment pas	
22.	Vous sentir inférieur(e) aux autres	0 1 2 3 4

0 = Pas du tout
1 = Un peu
2 = Passablement
3 = Beaucoup
4 = Excessivement

23.	Nausées, douleurs ou malaises à l'estomac	0 1 2 3 4
24.	Sentiments qu'on vous observe ou qu'on parle de vous	0 1 2 3 4
25.	Difficulté à vous endormir	0 1 2 3 4
26.	Besoin de vérifier et de re-vérifier ce que vous faites	0 1 2 3 4
27.	Difficulté à prendre des décisions	0 1 2 3 4
28.	Peur de prendre l'autobus, le métro ou le train	0 1 2 3 4
29.	Difficulté à prendre votre souffle	0 1 2 3 4
30.	Bouffées de chaleur ou des frissons	0 1 2 3 4
31.	Besoin d'éviter certains endroits, certaines choses ou certaines activités parce qu'ils vous font peur	0 1 2 3 4
32.	Des blancs de mémoire	0 1 2 3 4
33.	Engourdissements ou picotements dans certaines parties du corps (i.e. bras, jambes, figure, etc.)	0 1 2 3 4
34.	L'idée que vous devriez être puni(e) pour vos péchés	0 1 2 3 4
35.	Sentiment de pessimisme face à l'avenir	0 1 2 3 4
36.	Difficulté à vous concentrer	0 1 2 3 4
37.	Sentiment de faiblesse dans certaines parties du corps	0 1 2 3 4
38.	Sentiment de tension ou de surexcitation	0 1 2 3 4
39.	Pensées en relation avec la mort	0 1 2 3 4
40.	Envie de frapper, d'injurier ou de faire mal à quelqu'un	0 1 2 3 4
41.	Envie de briser ou de fracasser des objets	0 1 2 3 4
42.	Tendance à l'anxiété en présence d'autres personnes	0 1 2 3 4
43.	Vous sentir mal à l'aise dans des foules - au centre d'achat ou au cinéma	0 1 2 3 4
44.	Ne jamais vous sentir près de quelqu'un d'autre	0 1 2 3 4
45.	Moments de terreur et de panique	0 1 2 3 4
46.	Vous disputer souvent	0 1 2 3 4

0 = Pas du tout
1 = Un peu
2 = Passablement
3 = Beaucoup
4 = Excessivement

47.	Nervosité lorsque vous êtes laissé(e) seul(e)	0 1 2 3 4
48.	Sentiment de ne pas être reconnu(e) à votre juste valeur	0 1 2 3 4
49.	Vous sentir tellement tendu(e) que vous ne pouvez pas rester en place	0 1 2 3 4
50.	Sentiment d'être bon(ne) à rien	0 1 2 3 4
51.	Sentiment que les gens vont profiter de vous si vous les laisser faire.	0 1 2 3 4
52.	Avoir des sentiments de culpabilité	0 1 2 3 4
53.	Avoir l'impression que votre esprit (tête) est dérangé(e)	0 1 2 3 4

Appendix 11 - Sexual Information Scale

Derogatis Sexual Functioning Inventory

Randomized Treatment Outcome Study

SEXUAL KNOWLEDGE

Below are some statements concerning general information about sexual functioning. Please read each statement carefully. Once you have read it, indicate whether you agree with the statement or not by marking TRUE for those you agree with, and FALSE for those you do not.

		TRUE	FALSE
1.	Usually men achieve orgasm more quickly than women.	T	F
2.	Having intercourse during menstruation is not a healthy practice.	T	F
3.	The penis must be erect before ejaculation may occur.	T	F
4.	Simultaneous orgasm is not necessary for a good sexual relationship.	T	F
5.	Masturbation by either partner is an indicator of poor marital adjustment.	T	F
6.	A woman who has had a hysterectomy can no longer experience orgasm.	T	F
7.	Men reach the peak of their sexual drive in their late teens while women reach their peak during their 30's.	T	F
8.	A woman can become pregnant during menstruation.	T	F
9.	Most men and women lose interest in sex after age 60.	T	F
10.	A male's orgasm is more satisfying than a female's orgasm.	T	F
11.	The prophylactic (rubber) protects against conception and against venereal disease.	T	F

12. Lubrication in the female shows sexual excitement like the male's erection. T F

13. Oral-genital sex is unhealthy because it enhances the possibility of contracting venereal disease. T F

14. Women who have fantasies during intercourse are dissatisfied with their sex lives. T F

15. Frequency of intercourse is an accurate measure of success of a relationship. T F

16. A woman may be brought to orgasm by manual stimulation of her genitals. T F

17. Menopause in a woman creates a sharp reduction in her sexual drive. T F

18. Women desire sex about as frequently as men. T F

19. An effective form of contraception is douching after intercourse. T F

20. After intercourse there is a period when a man cannot respond to sexual stimulation. T F

21. Females can maintain a sexual response through multiple orgasms. T F

22. Most women are able to enjoy sex even without experiencing orgasm. T F

23. The bigger the penis the more satisfying it is to the female in intercourse. T F

24. A woman can no longer become pregnant once menopause has begun. T F

25. Erection in the male is brought about by congestion of blood in the penis. T F

26. The clitoris is not a particularly sensitive area of the female's genitals. T F

INSTRUCTIONS

Dans ce questionnaire, qui porte sur vos pensées et vos sentiments, vous serez appelé à nous renseigner sur certaines de vos attitudes et opinions, et à nous donner des renseignements concernant certaines de vos expériences sexuelles. Vos réponses seront confidentielles et seuls les membres de l'équipe qui s'occupent directement de la présente recherche pourront y avoir accès. A moins que vous n'en fassiez la demande expresse, ces renseignements ne seront divulgués à personne d'autre. Le présent inventaire comprend dix sections dont chacune vous demande quelque chose de légèrement différent. Dans certaines sections, vous aurez ainsi à répondre à des questions, tandis que dans d'autres, vous devrez vous décrire.

Chaque section comporte une brève description de ce que vous aurez à faire. Veuillez lire les énoncés attentivement et répondre à chacun d'eux.

SECTION I

Voici quelques énoncés concernant l'information générale sur la physiologie sexuelle. Une fois que vous les aurez lus attentivement, indiquez si vous êtes d'accord ou non avec chacun en cochant votre réponse (VRAI ou FAUX) dans la colonne appropriée.

		VRAI	FAUX
1.	Habituellement, les hommes atteignent l'orgasme plus rapidement que les femmes.	0	0
2.	Il n'est pas sain d'avoir des relations sexuelles pendant les menstruations.	0	0
3.	Le pénis doit être en érection avant que l'éjaculation puisse se produire.	0	0
4.	L'orgasme simultané n'est pas nécessaire à une bonne relation sexuelle.	0	0
5.	Le fait de se masturber est signe d'un mauvais ajustement conjugal.	0	0
6.	La femme qui a eu une hystérectomie ne peut plus avoir d'orgasme.	0	0
7.	Les hommes atteignent le sommet de leur besoin sexuel à la fin de l'adolescence tandis que les femmes atteignent le leur au cours de la trentaine.	0	0
8.	Une femme peut devenir enceinte même en étant menstruée.	0	0
9.	La plupart des hommes et des femmes perdent tout désir sexuel après 60 ans.	0	0

	VRAI	FAUX
10. L'orgasme de l'homme est plus satisfaisant que celui de la femme.	0	0
11. Le préservatif (condom) empêche la conception et protège contre les maladies transmises sexuellement (vénériennes).	0	0
12. La lubrification vaginale chez la femme est signe d'excitation sexuelle tout comme l'érection chez l'homme.	0	0
13. La sexualité bucco-génitale est malsaine parce qu'elle augmente la possibilité de contracter une maladie transmise sexuellement.	0	0
14. Les femmes qui ont des fantaisies pendant les relations sexuelles sont insatisfaites de leur vie sexuelle.	0	0
15. La fréquence des relations sexuelles d'un couple est une bonne mesure du succès de sa relation.	0	0
16. Une femme peut atteindre l'orgasme par stimulation de ses organes génitaux.	0	0
17. La ménopause entraîne chez la femme une diminution marquée de son besoin sexuel.	0	0
18. Les femmes ont envie de rapports sexuels aussi souvent que les hommes.	0	0
19. La douche vaginale après le coit est une forme efficace de contraception.	0	0
20. Après le coit, il existe une période au cours de laquelle l'homme ne peut répondre à la stimulation sexuelle.	0	0
21. Les femmes peuvent maintenir leur excitation sexuelle en ayant plusieurs orgasmes.	0	0
22. La plupart des femmes peuvent aimer les rapports sexuels même si elles n'atteignent pas l'orgasme.	0	0
23. Plus le pénis est gros, plus le coit est satisfaisant pour la femme.	0	0
24. Une fois sa ménopause commencée, une femme ne peut plus devenir enceinte.	0	0

	VRAI	FAUX
25. L'érection (chez l'homme) est causée par un afflux de sang dans le pénis.	0	0
26. Le clitoris n'est pas une partie particulièrement sensible des organes génitaux de la femme.	0	0

Appendix 12 - Sexual History Form

Randomized Treatment Outcome Study

Name:_____ Date:_____

SEXUAL HISTORY FORM

Please circle the most appropriate response to each question.

1. How frequently do you and your partner have sexual intercourse or activity?

1)	more than once a day	5)	once a week
2)	once a day	6)	once every two weeks
3)	3 or 4 times a week	7)	once a month
4)	twice a week	8)	less than once a month
		9)	not at all

2. How frequently would you like to have sexual intercourse or activity?

l)	more than once a day	6)	once every two weeks
2)	once a day	7)	once a month
3)	3 or 4 times a week	8)	less than once a month
4)	twice a week	9)	not at all
5)	once a week		

3. Who usually initiates sexual intercourse or activity?

l)	I always do	4)	my partner usually does
2)	I usually d	5)	my partner always does
3)	my partner and I initiate about equally often		

4. Who would you ideally like to initiate sexual intercourse or activity?

l)	myself, always	4)	my partner, usually
2)	myself, usually	5)	my partner always
3)	my partner and I equally often		

5. How often do you masturbate (bring yourself to orgasm in private)?

l)	more than once a day	6)	once every two weeks
2)	once a day	7)	once a month
3)	3 or 4 times a week	8)	less than once a month
4)	twice a week	9)	not at all
5)	once a week		

6. For how many years have you and your partner been having sexual intercourse?

1)	less than 6 months	4)	4 to 6 years
2)	less than 1 year	5)	7 to 10 years
3)	1 to 3 years	6)	more than 10 years

7. For how long do you and your partner usually engage in sexual foreplay (kissing, petting, etc.) before having intercourse?

1)	less than 1 minute	5)	11 to 15 minutes
2)	1 to 3 minutes	6)	16 to 30 minutes
3)	4 to 6 minutes	7)	30 minutes to one hour
4)	7 to 10 minutes		

8. How long does intercourse usually last, from entry of the penis to the male's orgasm/climax?

1)	less than 1 minute	6)	11 to 15 minutes
2)	1 to 2 minutes	7)	15 to 20 minutes
3)	2 to 4 minutes	8)	20 to 30 minutes
4)	4 to 7 minutes	9)	more than 30 minutes
5)	7 to 10 minutes		

9. Overall, how satisfactory to you is your sexual relationship with your partner?

1)	extremely unsatisfactory	4)	slightly satisfactory
2)	moderately unsatisfactory	5)	moderately satisfactory
3)	slightly unsatifactory	6)	extremely satisfactory

10. Overall, how satisfactory do you think your sexual relationship is to your partner?

1)	extremely unsatisfactory	4)	slightly satisfactory
2)	moderately unsatisfactory	5)	moderately satisfactory
3)	slightly unsatisfactory	6)	extremely satisfactory

11. When your partner makes sexual advances, how do you usually respond?

1)	I usually accept with pleasure	3)	often refuse
2)	accept reluctantly	4)	usually refuse

12. If you try, is it possible to reach orgasm (sensation of climax) through masturbation?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time	5)	never
3)	sometimes(about 50% of the time	6)	have never tried

13. If you try, is it possible for you to reach orgasm (sensation of climax) through having your genitals caressed by your partner?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried

14. If you try, is it possible for you to reach orgasm (sensation of climax) through sexual intercourse?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried

15. What is your usual reaction to erotic or pornographic materials (e.g. pictures, movies, books?)

1)	greatly aroused	3)	not aroused
2)	somewhat aroused	4)	negative (disgusted, repulsed, etc.)

16. Does the male have any trouble getting an erection before intercourse begins?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of the time)

17. Does the male have any trouble keeping an erection once intercourse has begun?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of of the time)

18. (WOMEN ONLY) Can you reach orgasm (sensation of climax) through stimulation of your genitals by an electric vibrator or any other means (i.e., running water, rubbing with some object, etc.)?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried to

19. (WOMEN ONLY) Can you reach orgasm during sexual intercourse if, at the same time, your genitals are being caressed (by yourself or your partner with a vibrator, etc.)?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried

20. (WOMEN ONLY) When you have sex with your mate (including foreplay and intercourse) do you notice some of these things happening: your breathing and pulse speed up, wetness in your vagina, pleasurable sensations in your breasts and genitals?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried

21. (MEN ONLY) Do you ever ejaculate without any pleasurable sensation in your penis?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)	6)	have never tried

THE REMAINING QUESTIONS ARE TO BE ANSWERED BY BOTH MEN AND WOMEN

22. Does the male ejaculate (climax) without having a full, hard erection?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of the time)

23. Does the male ever reach orgasm while he is trying to enter the vagina with his penis?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of the time)

24. Is the female's vagina so "dry" or "tight" that intercourse cannot occur?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of the time)

25. Do you feel pain in your genitals (sexual parts) during intercourse?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25% of the time)	6)	nearly always (over 90% of the time)

26. How often do you experience sexual desire (this may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.)?

1)	more than once a day	6)	once every two weeks
2)	once a day	7)	once a month
3)	3 or 4 times a week	8)	less than once a month
4)	twice a week	9)	not at all
5)	once a week		

27. When you have sex with your partner do you feel sexually aroused (e.g., feeling "turned on", pleasure, excitement)?

1)	nearly always (over 90% of the time)	4)	seldom (about 25% of the time)
2)	usually (about 75% of the time)	5)	never
3)	sometimes (about 50% of the time)		

28. When you have sex with your partner, do you have negative emotional reactions (e.g., fear, disgust, shame or guilt)?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25%of the time)	6)	nearly always (over 90% of the time)

29. Does the male climax without ejaculation (semen coming out of the penis)?

1)	never	4)	sometimes (50% of the time)
2)	rarely (less than 10% of the time)	5)	usually (75% of the time)
3)	seldom (less than 25%of the time)	6)	nearly always (over 90% of the time)

Nom:_____ Date:_____

FORMULAIRE D'HISTOIRE SEXUELLE

Veuillez indiquer la réponse la plus appropriée à chacune des questions suivantes.

1. A quelle fréquence avez-vous des activités ou des relations sexuelles avec votre partenaire?

   1) Plus d'une fois par jour
   2) Une fois par jour
   3) De 3 à 4 fois par semaine
   4) Deux fois par semaine
   5) Une fois par semaine
   6) Une fois chaque deux semaines
   7) Une fois par mois
   8) Moins d'une fois par mois
   9) Jamais

2. A quelle fréquence aimeriez-vous avoir des relations ou des activités sexuelles?

   1) Plus d'une fois par jour
   2) Une fois par jour
   3) De 3 à 4 fois par semaine
   4) Deux fois par semaine
   5) Une fois par semaine
   6) Une fois chaque deux semaines
   7) Une fois par mois
   8) Moins d'une fois par mois
   9) Jamais

3. Qui est habituellement l'initiateur de vos relations ou activités sexuelles?

   1) Toujours moi
   2) Moi, habituellement
   3) Ma/mon partenaire et moi-même en proportion assez égale
   4) Ma/mon partenaire, habituellement
   5) Toujours ma/mon partenaire

4. Par qui préféreriez-vous que vos relations ou activités sexuelles soient initiées?

   1) Toujours moi
   2) Moi, habituellement
   3) Ma/mon partenaire et moi-même en proportion assez égale
   4) Ma/mon partenaire
   5) Toujours ma/mon partenaire

5. A quelle fréquence vous masturbez-vous?

   1) Plus d'une fois par jour
   2) Une fois par jour
   3) De 3 à 4 fois par semaine
   4) Deux fois par semaine
   5) Une fois par semaine
   6) Une fois chaque deux semaines
   7) Une fois par mois
   8) Moins d'une fois par mois
   9) Jamais

6. Depuis combien d'années avez-vous des relations sexuelles avec votre partenaire?

   1) Moins de 6 mois
   2) De 6 mois à un an
   3) De 1 à 3 ans
   4) De 4 à 6 ans
   5) De 7 à 10 ans
   6) Plus de 10 ans

7. Combien de temps durent habituellement vos "jeux préliminaires" avant d'avoir une relation sexuelle?

1) Moins d'une minute
2) De 1 à 3 minutes
3) De 4 à 7 minutes
4) De 8 à 10 minutes
5) De 11 à 15 minutes
6) De 16 à 20 minutes
7) De 30 minutes à une heure

8. Quelle est la durée moyenne de vos relations sexuelles habituellement, c'est-à-dire, de la pénétration jusqu'à l'orgasme de monsieur?

1) Moins d'une minute
2) De 1 à 2 minutes
3) De 2 à 4 minutes
4) De 4 à 7 minutes
5) De 7 à 10 minutes
6) De 11 à 15 minutes
7) De 15 à 20 minutes
8) De 20 à 30 minutes
9) Plus de 30 minutes

9. Dans l'ensemble, jusqu'à quel point diriez-vous que vos relations sexuelles avec votre partenaire sont satisfaisantes pour vous?

1) Extremement insatisfaisantes
2) Modérément insatisfaisantes
3) Légèrement insatisfaisantes
4) Légèrement satisfaisantes
5) Modérément satisfaisantes
6) Extremement satisfaisantes

10. Dans l'ensemble, jusqu'à quel point diriez-vous que vos relations sexuelles avec votre partenaire sont satisfaisantes pour elle/lui?

1) Extremement insatisfaisantes
2) Modérément insatisfaisantes
3) Légèrement insatisfaisantes
4) Légèrement satisfaisantes
5) Modérément satisfaisantes
6) Extremement satisfaisantes

11. Quand votre partenaire vous fait des avances, comment répondez-vous habituellement?

1) J'accepte habituellement avec plaisir
2) J'accepte à contrecoeur
3) Je refuse souvent
4) Je refuse habituellement

12. Si vous essayez, vous est-il possible d'atteindre l'orgasme par la masturbation?

1) Presque toujours, plus de 90% du temps.
2) Habituellement, environ 75% du temps.
3) Parfois, environ 50% du temps
4) Rarement, envrion 25% du temps
5) Jamais
6) Je n'ai jamais essayé

13. Si vous essayez, vous est-il possible d'atteindre l'orgasme grâce aux caresses que votre partenaire vous fait aux organes génitaux?

1) Presque toujours, plus de 90% du temps
2) Habituellement, environ 75% du temps
3) Parfois, environ 50% du temps
4) Rarement, environ 25% du temps
5) Jamais
6) Je n'ai jamais essayé

14. Si vous essayez, vous est-il possible d'atteindre l'orgasme par la relation sexuelle?

1)	Presque toujours, plus de 90% du temps	4)	Rarement, environ 25% du temps
2)	Habituellement, environ 75% du temps	5)	Jamais
3)	Parfois, environ 50% du temps	6)	Je n'ai jamais essayé

15. Quelle est votre réaction habituelle à du matériel érotique ou pornographique?

1)	Très excité	3)	Pas excité
2)	Quelque peu excité	4)	Réaction négative de dégoût, répulsion, etc.

16. Est-ce que monsieur a de la difficulté à obtenir une érection avant le début de la relation sexuelle?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

17. Est-ce que monsieur a de la difficulté à conserver une érection avant le début de la relation sexuelle?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

18. (POUR FEMMES SEULEMENT) Pouvez-vous atteindre l'orgasme par la stimulation de vos organes génitaux à l'aide d'un vibrateur ou d'autres moyens tels que l'eau courante, frottement d'un objet, etc.?

1)	Presque toujours, plus de 90% du temps	4)	Rarement, environ 25% du temps
2)	Habituellement, environ 75% du temps	5)	Jamais
3)	Parfois, environ 50% du temps	6)	Je n'ai jamais essayé

19. (POUR FEMMES SEULELMENT) Pouvez-vous atteindre l'orgasme durant la relation sexuelle si vos organes génitaux sont caressés en même temps (par vous-même, ou votre partenaire, un vibrateur, etc.)?

1)	Presque toujours, plus 90% du temps	4)	Rarement, environ 25% du temps
2)	Habituellement, environ 75% du temps	5)	Jamais
3)	Parfois, environ 50% du temps	6)	Je n'ai jamais essayé

20. (POUR FEMMES SEULEMENT) Quand vous faites l'amour avec votre partenaire ("jeux préliminaires" et relation sexuelle compris), remarquez-vous que certaines des choses suivantes vous arrivent: accélération de votre respiration et de votre pouls, lubrication de votre vagin, sensations plaisantes dans vos seins et vos organes génitaux?

1)	Presque toujours, plus de 90% du temps	4)	Rarement, environ 25% du temps
2)	Habituellement, environ 75% du temps	5)	Jamais
3)	Parfois, environ 50% du temps	6)	Je n'ai jamais essayé

21. (POUR HOMMES SEULEMENT) Vous arrive-t-il d'éjaculer sans avoir de sensation agréable au pénis?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

LES QUESTIONS SUIVANTES S'ADRESSENT A L'HOMME ET A LA FEMME

22. Est-ce qu'il arrive à monsieur d'éjaculer sans avoir une érection complète, dure?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

23. Est-ce qu'il arrive à monsieur d'atteindre l'orgasme alors qu'il tente une pénétration?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

24. Est-ce que la pénétration est impossible en raison du manque de lubrification ou de la contraction du vagin?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

25. Ressentez-vous de la douleur aux organes génitaux durant la relation sexuelle?

1)	Jamais	4)	Parfois, 50% du temps
2)	Rarement, moins de 10% du temps	5)	Habituellement, 75% du temps
3)	A l'occasion, moins de 25% du temps	6)	Presque toujours, plus de 90% du temps

26. A quel fréquence ressentez-vous du désir sexuel? Il peut s'agir d'un désir de faire l'amour, de projeter de faire l'amour, de se sentir frustré(e) sexuellelment du au manque d'activité sexuelle, etc.

1) Plus d'une fois par jour
2) Une fois par jour
3) De 3 à 4 fois par semaine
4) Deux fois par semaine
5) Une fois par semaine
6) Une fois chaque deux semaines
7) Une fois par mois
8) Moins d'une fois par mois
9) Jamais

27. Quand vous faites l'amour avec votre partenaire, est-ce que vous vous sentez excité(e) sexuellement?

1) Presque toujours, plus de 90% du temps
2) Habituellelment, environ 75% du temps
3) Parfois, environ 50% du temps
4) Rarement, environ 25% du temps
5) Jamais
6) Je n'ai jamais essayé

28. Lorsque vous faites l'amour avec votre partenaire, ressentez-vous des réactions émotives négatives comme la peur, le dégoût, la honte ou la culpabilité?

1) Jamais
2) Rarement, moins de 10% du temps
3) A l'occasion, moins de 25% du temps
4) Parfois, 50% du temps
5) Habituellement, 75% du temps
6) Presque toujours, plus de 90% du temps

29. Est-ce qu'il arrive à monsieur d'atteindre l'orgasme sans éjaculer (sans sperme qui sort du pénis)?

1) Jamais
2) Rarement, moins de 10% du temps
3) A l'occasion, moins de 25% du temps
4) Parfois, 50% du temps
5) Habituellement, 75% du temps
6) Presque toujours, plus de 90% du temps

Appendix 13 - Standardized Gynecological Examination Form

Randomized Treatment Outcome Study

GYNECOLOGICAL EXAMINATION

Date _____ Date of last intercourse_____

Subject #_____ Gynecologist _____

Gynecologist pain rating

0 1 2 3
no pain mild moderate severe

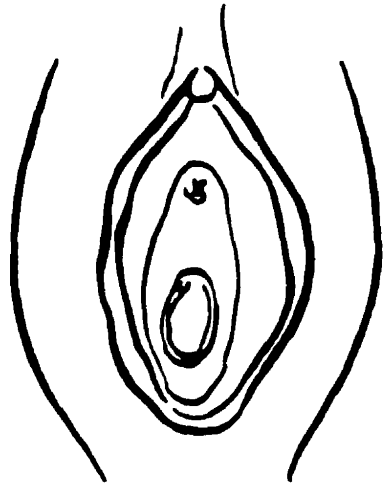
Patient pain rating

0 1 2 3 4 5 6 7 8 9 10
no pain worst pain ever

Erythema rating

0 1 2 3
none mild moderate severe

VULVA



©

PAIN RATING

	RT (gyne)	(pt)	LT (gyne)	(pt)	MIDLINE (gyne)	(pt)
Labia majora	—	—	—	—	—	—
Labia minora	—	—	—	—	—	—

PAIN RATING

Vestibule (gyne)

/12

9-12 ___ ___ 12-3

6-9 ___ ___ 3-6

/6

Vestibule (pt)

/12

9-12___ ___12-3

6-9___ ___3-6

/6

REMANANT OF THE HYMEN

Vestibule

/12

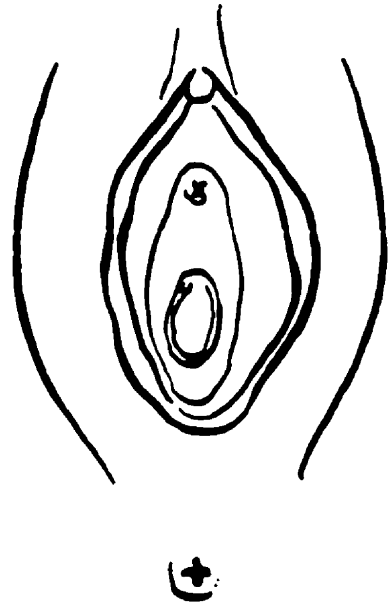
9-12 ___ ___ 12-3

6-9 ___ ___ 3-6

/6

ERYTHEMA RATING _____

LESIONS/EROSION/SCARRING/MICROPAPILLOMA/CONDYLOMA (code as L/E/S/M/C)



Other significant clinical findings in vulva

VAGINA

PAIN RATING

Anterior vaginal wall (bladder)

(gyne) (pt)

____ ____

	(gyne) (pt)	(gyne) (pt)
Pubococcygeal muscle	Rt ___ ___	Lt ___ ___
Uterosacral ligament	Rt ___ ___	Lt ___ ___

Muscular contractions (outer third, levator ani)

(gyne) (pt)

___ ___ Before examination

___ ___ Touching the vulva

___ ___ Insertion of speculum

___ ___ Insertion of finger

VAGINAL ATROPHY INDEX

	Score		
	1	2	3
Skin elasticity and turgor	Poor	Fair	Excellent
Pubic hair	Sparse	Normal	
Labia	Atrophic, dry	Full	
Introitus	< 1 fingerbreadth	1 fingerbreadth	2 fingerbreadths
Vaginal mucosa	Thin, friable	Smooth	Rugated
Vaginal depth	Shortened	Normal	

Total VAI score ____

PROLAPSED MUCOSA ____

Other significant clinical findings in vagina

UTERUS

PAIN RATING

(gyne) (pt)

___ ___ cervix without motion

___ ___ corpus without motion

___ ___ cervix with motion

___ ___ corpus with motion

Pain at vaginal examination alone ____

Pain at bimanual examination ____

mobile uterus ___

immobile uterus ___

cervical ectropion	yes	no	don't know	
cervical polyp	yes	no	don't know	
prolapsed uterus	yes	no	don't know	1 2 3
fibroids	yes	no	don't know	
anteverted uterus	yes	no	don't know	
intermediate uterus	yes	no	don't know	
retroverted uterus	yes	no	don't know	

Other significant clinical findings in the uterus or cervix

ADNEXAE

felt ___ not felt ___

mobile ___ immobile ___

PAIN RATING

	(gyne) (pt)	(gyne) (pt)
without motion	Rt ___ ___	Lt ___ ___
with motion	Rt ___ ___	Lt ___ ___

Pain at vaginal examination alone ____

Pain at bimanual examination ____

Other significant clinical findings in adnexae

PAIN RELATED DIAGNOSES
(please rank order your diagnoses)

No findings linked to dyspareunia	____
Vulvar vestibulitis syndrome	____
Vaginal atrophy	____
Infection	____
Bladder sensitivity/complications	____
Muscular contraction/tension	____
Prolapsed uterus	____
Scarring from previous incision	____
Vulvar erosion/lesions	____
Fibroids	____
Endometriosis	____
Cysts	____
Tender utero-sacral ligaments	____
Tender uterus	____
Retroverted uterus	____
Polyps	____
Tender ovaries	____
Cervical eversion	____
Cervical inflammation	____
Condyloma	____
Atypical cell changes in PAP	____
Micropapilloma	____
Monolilial vaginitis	____
Squamous metaplasia	____
Congenital anatomical anomaly	____
Candidiasis	
Other (please specify)	____

_____

NON-PAIN RELATED DIAGNOSES

1. _____
2. _____
3. _____
4. _____
5. _____

Appendix 14 - Instructions for Participant Treatment Compliance

Randomized Treatment Outcome Study

More information about the treatment study...

1. Your participation in the Vulvar Vestibulitis Syndrome Treatment Study is appreciated! This research endeavor is a large-scale study put together by a multidisciplinary team of researchers and clinicians specialized in painful intercourse (dyspareunia) and funded by Health Canada and Pfizer company. As you know, this study is trying to determine which treatments are the most effective in alleviating pain caused by the Vulvar Vestibulitis Syndrome. Over one-hundred and eighty women from the Montreal area will take part in the initial assessment procedure of this study, and ninety women will be selected to undergo treatment. It is hoped that you will personally benefit from your participating in the study and that many other women with VVS may also greatly benefit from your contribution.

2. Your full cooperation is very important to the study. We hope that you will follow all study recommendations contained in this brochure, so that working together, we may obtain the most accurate results. If anything is not clear, please ask the appropriate person to clarify it for you, be it your surgeon, therapist, the research coordinator Janet Bradley, or Sophie Bergeron. *Do not hesitate to ask questions*. Please keep in mind that to reduce bias on our part, Janet Bradley is blind to the treatment condition you have been assigned to, i.e., she does not know what treatment you are receiving, as she is the independent assessor of the effectiveness of the treatments and conducts the assessment interviews. Help us keep it that way by not telling her which treatment you were assigned to.

3. Keep appointments. The biofeedback and pain management treatment sessions are very important. If you are not able to keep a scheduled appointment, call your therapist in advance and make a new appointment. The same goes for the post-treatment and 6-month follow-up assessments (including gynecological exams and interview). If you are not able to keep a scheduled appointment for those assessments, call Janet Bradley (398-5323) as soon as possible and reschedule with her.

4. Do your homework. Homework assignments given to you in the biofeedback and pain management conditions are very important to the success of the treatment. If you are unclear about how to perform the home exercises, ask your therapist for further explanations. The therapists are there to help you.

5. Change in Residence. If you are moving, please let Janet Bradley know of your change of address and telephone number as soon as possible.

Vacations. If you are planning to take a vacation during the treatment period of the biofeedback and pain management conditions, please let your therapist know in advance so that they can either try to make up for the canceled appointment(s) or they can keep you up to date on what has been going on in the group.

6. Other Treatments. Please refrain from undergoing any other treatments for VVS while you are participating in the study (this includes the 6-month follow-up period).

7. **Daily Pain Ratings.** Don't forget to fill in your daily pain rating forms at the times indicated on your instructions sheet accompanying them.

To reach Janet Bradley or Sophie Bergeron, call 398-5323. Please keep this information sheet as a reference until the end of the study.

D'autres informations concernant l'étude de traitement...

1. Votre participation à l'Étude de Traitement du Syndrome de la Vestibulite Vulvaire est appréciée! Ce projet de recherche constitue une étude à grande échelle conçue et organisée par une équipe multidisciplinaire de chercheurs et de cliniciens spécialistes des relations sexuelles douloureuses (dyspareunie) et subventionnés par Santé Canada et la compagnie Pfizer. Comme vous le savez, cette étude vise à déterminer quels traitements sont les plus efficaces quant au soulagement de la douleur causée par le Synrome de la Vestibulite Vulvaire. Plus de cent-quatre-vingt femmes de la région de Montréal prendront part à la procédure d'évaluation initiale, et quatre-vingt-dix femmes seront sélectionnées pour recevoir un des traitements que nous offrons. Il est souhaité que vous bénéficierez personellement de votre participation à l'étude et que plusieurs autres femmes souffrant du SVV bénéficieront elles aussi grandement de votre contribution.

2. Votre pleine coopération est très importante pour l'étude. Nous espérons que vous suivrez toutes les recommendations contenues dans ce mémo afin que, travaillant ensemble, nous obtenions les résultats les plus exacts possibles. Si quelquechose n'est pas clair, demandez des explications additionnelles à la personne appropriée, que ce soit votre chirurgien(ne), thérapeute, la coordonatrice de recherche Janet Bradley, ou Sophie Bergeron. *N'hésitez pas à poser des questions.* Rappelez-vous que dans le but de prévenir un biais de notre part, Janet Bradley est "aveugle" au traitement auquel vous avez été assignée, c'est-à-dire qu'elle ne sait pas quel traitement vous recevez. Ceci est nécessaire puisqu'elle est l'évaluatrice indépendante de l'efficacité des traitements et est donc responsable des entrevues d'évaluation. Aidez-nous à maintenir cet état de choses en ne lui disant pas à quel traitement vous avez été assignée.

3. Gardez vos rendez-vous. Les sessions de traitement de biofeedback et de gestion de la douluer sont très importantes. Si vous n'êtes pas en mesure de garder un rendez-vous, communiquez avec votre thérapeute à l'avance et reprenez un autre rendez-vous. Même chose pour les évaluations post-traitement et 6-mois-de-suivi (incluant les examens gynécologiques et une entrevue). Si vous êtes dans l'impossibilité de garder un rendez-vous pour ces évaluations, communiquez avec Janet Bradley (398-5323) à l'avance et reprenez un autre rendez-vous avec elle.

4. Faites vos exercices à la maison. Les exercices faisant partie des traitements de biofeedback et de gestion de la douleur sont une composante essentielle du succès du traitement. Si certains de ces exercices ne sont pas clairs pour vous, demandez des explications additionnelles à votre thérapeute. Les thérapeutes sont là pour vous aider.

5. Déménagement. Si vous déménagez, prenez soin de laisser votre nouvelle adresse et votre nouveau numéro de téléphone à Janet Bradley le plus tôt possible.

Vacances. Si vous planifiez prendre des vacances pendant la période de traitement du biofeedback ou de la gestion de la douleur, prenez soin d'aviser votre thérapeute à l'avance pour qu'elle puisse soit reprendre le(s) rendez-vous manqué, soit vous informer de ce qui s'est passé dans le groupe de traitement pendant votre absence.

6. Autres Traitements. S.V.P. n'utilisez pas d'autres traitements pour le Syndrome de la Vestibulite Vulvaire pendant que vous participez à l'étude (ceci inclut la période de suivi de 6 mois).

7. Inventaire Quotidien de la Douleur. N'oubliez pas de remplir vos formulaires selon les dates indiquées sur la feuille d'instructions incluse dans la même enveloppe que vos formulaires.

Pour communiquer avec Janet Bradley ou Sophie Bergeron, appelez au 398-5323. S.V.P. conservez ce mémo d'information comme référence jusqu'à la fin de l'étude.

Appendix 15 - Treatment Expectancies Questionnaire

Randomized Treatment Outcome Study

Treatment expectancies

Subject #: _____ Therapist: _____

Date: _____

The following questions should be answered based on your personal opinion.

1. Up to what point do you think the treatment you are receiving is logical in terms of its efficacy in alleviating vulvar vestibulitis syndrome?

0	1	2	3	4	5	6	7	8	9	10
not at all										totally logical

2. How confident are you that the present treatment will improve your pain condition?

0	1	2	3	4	5	6	7	8	9	10
not at all										totally confident

3. Please rank order the treatments offered in this study by your own order of preference (vestibulectomy, biofeedback, pain management).

first choice: _____
second choice: _____
third choice: _____

Attentes vis-à-vis du traitement

Sujet #: _____ Thérapeute: _____

Date: _____

Répondez aux énoncés suivants en vous basant sur votre opinion personnelle.

1. Selon vous, jusqu'à quel point le traitement que vous recevez est-il logique en termes de son efficacité à soulager la vestibulite vulvaire?

0	1	2	3	4	5	6	7	8	9	10
pas du tout										totalement logique

2. Jusqu'à quel point êtes-vous confiante que le présent traitement améliorera votre problème de douleur?

0	1	2	3	4	5	6	7	8	9	10
pas du tout										totalement confiante

3. Classez les traitements offerts dans cette étude par ordre de préférence (vestibulectomie, biofeedback, gestion de la douleur).

1er choix: _____
2e choix: _____
3e choix: _____

Appendix 16 - Treatment Manual

GCBT

Randomized Treatment Outcome Study

Treatment manual for cognitive-behavioral group therapy with women suffering from vulvar vestibulitis syndrome

Parts of this manual are adapted from Pain and Behavioral Medicine: A Cognitive-Behavioral Approach (Turk, Meichenbaum & Genest, 1983) and from Managing Pain Before it Manages You (Caudill, 1995).

Table of Contents

Handouts (English and French)

Study-related issues for therapist

Preparation

Prior to the beginning of treatment, the therapist will review the study files of all the participants assigned to her group. She will also read the review of the literature on vulvar vestibulitis syndrome by Bergeron, Binik, Khalifé and Pagidas (1997). During the course of the treatment, the therapist will have weekly sessions of 1-hour supervision with a specialist in cognitive-behavioral group therapy for chronic illnesses affecting sexual function - Dennis Kalogeropoulos, Ph.D.

Initial contact

Notification of participants as to the beginning date, time and location of the group therapy will be made over the telephone by the therapist one week prior to the first treatment session.

Rationale and overview of the cognitive-behavioral approach as applied to vulvar vesibulitis

Why a group?

Group cognitive-behavioral treatment has been shown to be as effective as individual therapy (e.g. Genest & Turk, 1979; Herman & Baptiste, 1981). Furthermore, it capitalizes on group processes such as cohesiveness, self-disclosure, and support. (Turk, Meichenbaum, & Genest, 1983).

Brief overview of the cognitive-behavioral approach as applied to the treatment of vulvar vestibulitis syndrome

Treatment goals. The purpose of this manual is not to provide a lengthy review of cognitive-behavioral and group therapy principles, as both therapists in this study have a strong background in cognitive-behavioral therapy, especially as it applies to sexual dysfunctions, and group work. We will thus only provide a brief overview of the goals of cognitive-behavioral group therapy for vulvar vestibulitis syndrome:

1) Reconceptualization of dyspareunia as a multidimensional pain disorder that is influenced, among other things, by thoughts, feelings, and behaviors.
2) Modification of thoughts, feelings, and behaviors associated with painful intercourse with a view to increase adaptive coping and to decrease maladaptive coping (e.g., catastrophization).
3) Consolidation of skills acquired during the therapy and maintenance of change.

Therapeutic process. The therapist will adhere, as much as possible, to the following guidelines:

1) Engender a collaborative working relationship with all participants in the group.
2) Use interventions that support and/or increase group cohesion (e.g. after a participant has revealed something about herself, ask the others if they have ever experienced anything similar).
3) Use a Socratic rather than a didactic approach.
4) Clarify any potential misconceptions by raising them and discussing them.
5) Use the participants' examples to illustrate what is meant by various concepts (e.g. how thoughts can affect pain).

6) Both validate and challenge the participants' view of their pain (e.g. "It is completely normal to feel this way... what might be another way of viewing the problem?).

Homework. An important part of cognitive-behavioral therapy is the assignment of homework. Here are the goals of the exercises that will be recommended to the participants:

1) To assess the cognitive, emotional and behavioral aspects of the participants' sexual function and intimate relationships and how these influence and are affected by the pain problem.
2) To examine the typical responses of significant others and the participants to painful intercourse.
3) To make the participants more aware of factors that exacerbate and alleviate their pain.
4) To help the participants identify maladaptive responses to painful intercourse.
5) To consolidate the use of coping procedures discussed during the group therapy sessions.
6) To illustrate to the participants and their significant others that progress can be made in managing their pain.
7) To serve as reinforcers and as enhancers of self-efficacy as the participants achieve goals.
8) To assist the therapist and participants in assessing progress.

For each homework assignment, the therapist will provide the rationale and an explanation of the exercise on paper (for them to bring home) as well as orally during the group session. The therapist will always ask if they have any questions. Address potential difficulties they might have with the homework. Emphasis should be placed on not giving up, on considering what may have contributed to the lack of success, and on the

importance of continued effort, with reinforcement of the effort, not just of success. Give participants some homework diary sheets (as a measure of compliance for us) that they will fill out as they go along.

Session by session guidelines

Session 1

Introduction of therapist and participants. (A) The therapist introduces herself. She will explain that she has read the participants' files and that she knows where everybody is at. She will emphasize initial individual differences and the ones that will be noticed as each member progresses. She will mention the following points: 1) participants should not compare themselves to the others too much as each will go at their own pace; 2) some exercises will be relevant for some, and irrelevant for others; 3) the support of the group will be important. The therapist will acknowledge participants' shyness re: talking about their sex life in a group, with women they hardly know. (B) The therapist asks participants to introduce themselves and suggests the following instructions: each participant can briefly describe their pain history, onset, impact on sexual functioning, current state of sexual functioning (e.g. frequency of intercourse, desire, etc.).

Explanation of the treatment plan. 1) The therapist will explain the nature of the program using specific, credible examples of how pain management works and how the mind plays an important role in pain perception. She will emphasize the credibility of the program: e.g., "these are techniques that are used at the Royal Victoria Hospital in the treatment of cancer pain, etc." E.g., "By now, you have probably been to a number of doctors who have suggested that the pain is all in your head. That is a common misconception about pain and it is nonsense. It surely does not help, and it simply is not

true. Your pain is real. The proper question is, what are the factors that influence the pain? At one time we used to think that pain was a simple matter: Something hurt your body and you felt pain. But it is just not that simple. Many different things affect the pain experience (e.g., surgery under hypnosis, athletes and dancers who do not feel pain until the end of a performance, people who walk on hot coals, etc.). Throughout this workshop, we will examine all the things that may be related to your pain so that we can select the best set of procedures to be used to reduce your pain and can help you have a more satisfactory and pleasant sex life. Some will improve by 50%, others by 75%; it will vary. Even if your pain doesn't go away completely, you'll be able to do more. To achieve these goals, it is important for you to understand that I do not have any magical techniques or procedures that will immediately take away your pain. Instead, we will work together to develop tools that you will use in your everyday life to better understand and eventually alleviate the pain."

2) She will give participants an outline of the 8 sessions and give them time to read it.

3) She will elicit information regarding the participants' expectations concerning the program and deal with their reservations, skepticism, etc.

4) She will answer questions about the nature of the program and the outline as well as clarify any misconceptions.

Education and discussion re: vulvar vestibulitis. The therapist will educate participants about vulvar vestibulitis syndrome (VVS). 1) She will give them the review of the literature on vulvar vestibulitis by Bergeron, Binik, Khalifé and Pagidas (1997) and tell them to read the article at home and to keep in mind that we will discuss it next week.

2) Information about vulvar vestibulitis syndrome:

-symptoms and diagnostic criteria: entry dyspareunia, pain during cotton-swab test, redness, pain during other activities such as tampon insertion, etc.

-mostly found in women between 18 and 30

-prevalence rate of up to 15%

-begins either from first intercourse attempt or later on, following repeated yeast infections or other trauma to the area, or for no apparent reason

-likely multifactorial etiology, although little is known: yeast infections, past trauma to the area, hormonal component, immunological component, central sensitization (nerve fibers and brain possibly overly sensitive to pain, in relation to past trauma)

-these participants will have already received education about treatment but you can raise the issue and answer their questions if they have any

-history of seeing many doctors; usually women think they are not normal; are ashamed; cannot talk about it to many people

-impact on sexual functioning (diminished desire and arousal, diminished frequency of intercourse, all of which are most probably a consequence of the pain); may lead to couple problems

-no psychological problems, no more sexual abuse than normal women (e. g. Meana, Binik, Khalifé and Cohen, 1997)

3) The therapist will ask participants if they recognize themselves in this description as well as elicit their reactions and normalize what they may be feeling.

4) The therapist will use the rubber model to identify the location of the pain; she will let everybody handle it and will answer questions.

Education and discussion re: phenomenon of pain. The therapist will educate participants about pain and discuss some of the myths of pain (write Myths 1 and 2 on the blackboard).

E.g. "There are various ideas or myths about pain that patients and their significant others often have. I am not sure if you believe these, but they are worth our going over and considering where they fit and do not fit with your own notions."

Malec, Glasgow, Ely, and Kling (1977) offer the following myths about pain:

1) *MYTH #1*: If physicians can't cure your pain or find out exactly what is causing it, then your pain must be in your imagination. FALSE.

"Besides, looking at it another way, all pain is "in your head." After all, your brain is in your head. The brain is what tells you if you hurt, how much you hurt, where you hurt, and what to do about it. Even when you hurt because you hit your thumb with a hammer, the pain is "in your head." This is why psychological methods of pain control work, because they involve your brain, which is the one who perceives pain. You can learn to keep pain from bothering you."

2) *MYTH #2.* If you can make your pain less by psychological self-control, then the pain was "all in your head" to begin with. FALSE.

"Although some of the outward signs of pain may be visible, pain is a private, individual experience. And because it is so private, so individual, no two people undergo exactly the same feelings of pain from the same source. Many things beside the *intensity of the stimulation* contribute to the experience of pain. On two different occasions, you may

experience quite different pain from exactly the same external stimulation (e.g. differences in pain ratings from the same stimulation, penile penetration and thrusting). Still another example: In several tribes, women in labor apparently experience no pain. They simply stop their work to have the baby and return to work immediately afterwards. Up until very recently, in North America the average hospital stay after birth was from 5 to 7 days. These women are not experiencing the intense, debilitating pain that is usual in our culture. Obviously, pain is influenced by many things."

3) The therapist can have the participants generate examples of their own to support the contention that pain is more than a consequence of the specific so-called physical cause.

E.g. " I have read in the interviews that many of you noticed that the pain varies depending on how aroused you are, how lubricated you are, which partner you are with, how anxious you are, etc."

4) The therapist, via discussion, can begin to get the participants thinking about how different factors affect the pain experience and highlight the variations in their current pain. At this point the intention is more to raise issues than to find solutions. The therapist's probes are designed to begin the reconceptualization process in which the participant plays an active role in contributing to her presenting problems and is not a helpless bystander or victim of the pain. As this reconceptualization emerges, one implication is that something could be done to change the behaviors, feelings, and thoughts that affect the pain experience.

Homework. THE THERAPIST GIVES PARTICIPANTS THE LOCATION EXERCISE AND PAIN DIARY HANDOUT.

1) *Localization exercise*. The therapist will explain the **rationale** of the location exercise: the goal is to gain more control over their pain; if they know exactly where it hurts, this will affect their perception of the pain. Furthermore, they can use this information to inform and educate their partners and to vary sexual activities.

How to do it: the therapist will instructs everybody to go home and locate the painful area themselves, with their fingers or with a cotton-swab tip; she will ask them to draw a picture of their genitals (using a mirror), highlighting the painful area. She will make sure they understand and will answer their questions. She should go over the exercise handout with them.

2) *Pain diary*. The therapist will explain the **rationale** of Pain Diary exercises: the goal is to better understand the pain and what influences it. They may have an intuitive understanding of this, but to actually see it on paper, with the pain ratings, will make it clearer and more concrete and will help in implementing the various treatment techniques. The pain intensity ratings will provide an opportunity to determine whether the pain intensity follows any particular pattern. The therapist and participants can consider memory aids for filling out the diary (e.g., placing reminders at strategic points, such as on the bedside table, in the washroom, etc.).

How to do it: the therapist will explain the Pain Diary exercises. She will make sure they understand and will answer their questions. She will go over the pain diary handout with them.

General infor re: partner. The therapist will suggest that participants share with their partner any information discussed in the group that they think might help him understand

VVS more and contribute to the pain management process (e.g. information about arousal, etc.).

Study-related issues. 1) The therapist will have participants fill out expectations form and pain questionnaires (explaining that these are for the purposes of the study). 2) She will give them the Daily Pain Monitoring forms (for the purposes of the study) and go over the instructions with them. 3) She will give them the "More info about the study..." handout. 4) She will give back participants copies of their signed consent form.

Session 2

Question period re: VVS article. The therapist will ask the participants whether they read the review article on VVS. Do they have any questions? Did they have their partners read it (if applicable)? The therapist can take a few minutes to discuss the article with them.

Review of homework. 1) The therapist will ask the participants if they encounter any problems with the pain diary. Do they envision any potential problems? She can help them generate concrete solutions (e.g. a reminder system because they keep forgetting to fill out the diary) and let them know that they will discuss the diary more in depth next week. 2) The therapist will review the pain location exercise. How did they feel while doing the exercise? What do they think of their genitals? She can discuss issues such as anatomy, appearance, smell, etc. Did they show the area to their partners? Is it clearer to them now? What impact might this have on their perception of pain? She should dispel any myths or unrealistic ideas they may have about their genitals (e.g. "vulvar vestibulitis has deformed my genitals").

Desensitization exercise. 1) The therapist will introduce the Betty Dodson video entitled self-loving and explain its **rationale**: There are two purposes to watching this video: 1) to desensitize them re: looking at their genitals, talking about their genitals, and more generally, masturbating. Again, this is all part of gaining more control over their pain, and this starts with knowing their genitals and being comfortable with them, and eventually knowing what gives them sexual pleasure. The therapist can warn them that some may find the content a bit crude, or shocking. We are not suggesting they go out and do the same as in the video; it is used as a desensitization tool. 2) to introduce masturbation: Many of them are avoiding all types of sexual activity. The therapist can explain to them that this is important as they need to renew with some form of sexual activity to try to find pleasure again in sexuality (to wake up their dormant sexuality). Masturbation is the activity during which they have the most control and also during which there is a good chance they will not experience pain. It is very important to start reexperiencing sexual pleasure, since now they may be associating their vulva and vagina only with pain. They need to start associating these body parts with pleasure again.

2) Therapist and participants will watch the first 1/2 hour of the video.

3) Therapist and participants can discuss the video. How did they feel? What did they think? Were they shocked? Surprised?

4) The therapist should suggest that they try the mirror/drawing exercise again; perhaps they will have a more positive perspective after having viewed this video.

Discussion: a different view of pain. The therapist will provide a reconceptualization of pain following the gate-control model, emphasizing that thoughts and feelings can exacerbate the pain experienced. 1) She will help the participants to develop a more

differentiated view - one that implies voluntary control by the participant over components of the pain. These components include (a) unpleasant physical sensations over which the participant may exert control, (b) pain-related thoughts and images, (c) pain-related feelings, and (d) pain-related behaviors. 2) To illustrate each component, the therapist should use the participants' own experiences or own data (pain diaries, etc.) and should thus encourage participants to offer their own examples.

E. g. from Karol, Doerfler, Parker, and Armentrout (1981): "Pain may begin with bodily damage or injury or with disease. A pain message from the site of injury is sent through a mechanism that works like a "gate to the brain." The brain then interprets this message. This gate can be partially or fully opened or closed, determining the amount of pain. A variety of physical, emotional, and mental factors may open or close the gate." The following can be discussed with the group, although the therapist should keep in mind that this model does not fully apply to painful intercourse. For this reason, she should not write it on the blackboard, but adapt it as much as possible to dyspareunia:

Factors that open the gate

1. Physical factors
    a. Extent of injury or trauma to the area
    b. Readiness of the nervous system to send pain signals.
    c. Inappropriate activity level.
2. Emotional stress
    a. Depression
    b. Anxiety
    c. Worry
    d. Tension
    e. Anger

3. Mental factors

a. Focusing on the pain

b. Boredom due to minimal involvement in life activities

c. Nonadaptive attitudes

Factors that close the gate

1. Physical factors

a. Medication

b. Counterstimulation (cold, massage, acupuncture)

c. Appropriate activity level

2. Relative emotional stability

a. Relaxation

b. Positive emotions (e.g., happiness, optimism).

c. Adequate rest

3. Mental factors

a. Life involvement and increased interest in life activities

b. Intense concentration

c. Adaptive attitudes

3) The therapist can emphasize the potential for the participants to control pain and discomfort.

Homework. The therapist will introduce the *breathing exercise*, starting with its **rationale**: "as many of you have noticed, the anticipation of pain creates anxiety, which has two consequences: (a) it inhibits arousal, which in turn inhibits lubrication, which increases the pain upon penetration; (b) it often contributes to an involuntary contraction of the vaginal muscles, which again, makes penetration a lot more painful, and sometimes

impossible (write those 2 points on the blackboard in the form of a diagram). For these reasons, an important part of the treatment is to learn to reduce anxiety. One major way in which they will learn to do this is via a breathing/relaxation techniques.

For centuries humankind has been provided with instructions for bringing about a quieting response (the contrary of a stress response), called the 'relaxation response' (RR). This natural bodily reflex however does not happen automatically. It requires practice with certain mental techniques before it can be called upon to counter anxiety. Many techniques can bring about this natural response, although two simple steps are common to all of them: (a) focusing one's mind on a repetitive phrase, word, breath, or action; (b) adopting a passive attitude toward the thoughts that go through one's head. The physical effects of the RR can be divided into: (a) immediate changes, which occur while a person is focusing on a repetitive word, phrase, breath or action, and (b) long-term changes, which occur after repeated practice for at least a month, and are present even when a person is not sitting quietly practicing an RR technique. People report a decrease in anxiety and depression, as well as an ability to cope with life stressors. The key to bringing about RR is focused awareness. Your breathing can be the object of that focus. Normal breathing patterns can be disrupted by anxiety and pain.

There are two types of breathing: chest breathing (short, shallow breaths, characteristic of anxiety) and diaphragmatic or abdominal breathing (abdomen rising and falling, like babies, brings about a feeling of calm and relaxation). Before doing any other exercises in this therapy, you need to become aware of how you breathe. Place one hand on your breastbone and one hand on your belly button. Close your eyes and become aware of what is moving when you breathe in and out. If it is your abdomen, you are already breathing diaphragmatically. If it is your chest, you need to learn how to breathe from the abdomen. "

How to do it: Diaphragmatic breathing: "Place your hands just below your belly button. Close your eyes and imagine a balloon inside your abdomen. Each time you breathe in, imagine the balloon filling with air. Each time you breathe out, imagine the balloon collapsing." The therapist will practice it with them for about 5 minutes and ask them if they have any questions or concerns. She will ask them to practice diaphragmatic breathing at home. They can count 10 breaths and start again. They can try it for about 5 minutes a time, as often as possible, such as once a day. NO HANDOUT.

Session 3

Review of homework. The therapist will review the mirror/drawing exercise again: How was it different after having seen the video? Do they have any more comments about the video, their genitals, their discomfort, etc.?

Discussion re: pain diary. The therapist will continue educating participants about pain via their diary entries. She will have a look at the diaries of some participants and encourage them to share with each other their respective pain diary entries and then begin to speculate on reasons for the changes in pain levels. The group members themselves can begin to suggest some of the complex relationships among behavior, cognitions, affect, environmental events, and pain, which will form the basis for later interventions. The therapist can facilitate the achievement of insight into the possible connection between certain situational events, such as conflict, and the variability of pain, using clinically sensitive questions and the data gathered by the participants. The goal is for the participants to start entertaining the notion that the pain they experience is indeed complex and subject to a variety of influences. Throughout the discussion, the therapist can encourage group members to view the formulation of their problems and strategy planning as cooperative efforts, not as interpretations and techniques rigidly imposed on

them by the therapist. E.g. "You have all done a good job of filling in your pain diary. I wonder if you have noted anything special about what you have recorded. For example, some participants may find varying pain ratings: do you have some ideas as to why that might be? "

Impact of pain on thoughts, emotions and behaviors. The therapist will discuss the impact of pain on thoughts, feelings, physical sensations and behavior, and in return the impact that thoughts, feelings, and physical sensations such as arousal might have on the pain experience. She will explain to participants the details of the vicious cycle and continue to educate them about the impact of coital pain on desire, arousal and orgasm, having them generate their own examples: How has their sex life changed since the pain? How do they feel about these changes? What does having pain during intercourse mean to them?

Discussion re: avoidance of sexual activities and role of partner. The therapist will help participants to identify if they have been avoiding sex. She will work at breaking avoidance habit if some of them are avoiding (this will be an ongoing task throughout the therapy): How do they avoid sex? Do they have unrealistic beliefs or less adaptive attitudes about sex? She can use the different levels they are at to facilitate their learning from one another. What are some of the reasons why they avoid sex? Pain is one, but what about activities that are not painful? What sexual activities do not involve pain? Can they practice these? Can they show their partner how they masturbate so as to avoid any pain? The therapist can lead the discussion toward the partner's reactions to the pain. How might these contribute to the pain experience? Could they discuss these issues with their partner? The therapist should have them generate some potential ideas/solutions and suggest some herself if necessary. She can write some of these on the blackboard. She should potentiate their own coping skills and give them the opportunity to learn from one

another's coping skills, all the while emphasizing the potential they have to control their pain.

Discussion re: means that can be used to increase desire. The therapist will ask participants to think about ways to increase their desire for sex and write those on the blackboard and on a list that she will give back to them the following week. If they are shy about this, she can start generating ideas herself (e.g., fantasy rehearsal, erotic material, discussing their frustrations with their partner) and slowly bring them to do it themselves. She should use humor to dissipate their discomfort if any.

Homework. 1) The therapist will discuss the *breathing exercise* they practiced during the week and teach them a more formal breathing exercise; she will ask them to do it before the dilatation exercise that will be explained in a few minutes. She will make sure they understand and will answer their questions: What steps do they need to take to attain the goal of practicing the breathing exercises? Do they envision any potential problems? Can they think of solutions? "Breathing and relaxation exercises are not the same as relaxing via reading a book or listening to music; these activities do not bring about the RR".

How to do it: THE THERAPIST GIVES PARTICIPANTS THE BREATHING AND DILATATION EXERCISES HANDOUT. She goes over the handout with them and practices the exercise once with them for about 5 minutes.

2) **Rationale** for the *dilatation exercise*: "the goal is to desensitize yourself to the association of something inside your vagina and pain. Get acquainted with the feeling of having something in your vagina while not experiencing any pain and while in complete control of the situation.

How to do it: The therapist will explain the dilatation and ask them to do it once a day, preceded by the breathing exercise. The insertion should ideally be about 2 inches deep, but may start with less, depending on where they are at. They can use lubricant to facilitate the insertion (not KY jelly because it becomes sticky; it is preferable to use Astroglide). They can start with a cotton-swab if a finger is too difficult. They can use other things later on (zucchinis, carrots, etc.; use humor while mentioning this!).

Session 4

Review of homework. 1) The therapist will review the breathing exercise and the dilatation: Did they encounter any problems? How anxious did they feel? Did they notice if their vaginal muscles contracted when they tried to enter their finger? Can they generate solutions? 2) She will give them the list of ideas re: desire from last week's session. She will have them share their experiences with the group re: the application of some of the ideas they had concerning how to increase desire: Have they noticed any change in their desire? Did they discuss any of the suggestions with their partners?

Discussion re: how to increase arousal. 1) The therapist will ask participants at what point during sex do they experience arousal problems. This may vary considerably from one woman to the other. She will ask them to think about ways to increase their sexual arousal and write those on the blackboard and on a list for the following week, giving them the opportunity to learn from each other. She will add some suggestions herself if necessary and discuss ways to implement these: What might prevent them from implementing those changes (e.g. myth of simple, spontaneous sex). Do they foresee any problems with their partner in terms of the changes they want to make in their sex life? The therapist should suggest they discuss some of their feelings about this with their partners. 2) Could anything else besides anticipation of pain be inhibiting arousal? The therapist can have

them generate examples. E.g., issues with receiving pleasure, feeling guilty that they have pain and that their boyfriend or husband has to put up with a "dysfunctional partner", difficulties in communicating preferences, especially regarding new ways to diminish or avoid the pain, focusing only on the partner's arousal, negative body image, etc. The therapist should encourage them to address some of these issues with their partner.

Homework. THE THERAPIST GIVES PARTICIPANTS THE RELAXATION AND KEGEL EXERCISES HANDOUT.

How to do it: 1) The therapist will teach participants another *breathing exercise*, emphasizing that they should use whatever works best for them, only once they have tried all of the techniques that will be shown to them. She will go over the handout with them, practice the exercise once with them and answer their questions. Exercise: counting breaths to 10 for 10 minutes (count on the exhale) (see instructions on the handout).

2) **Rationale** of the *Kegel exercises*: " the goal of these exercises it to help you gain greater control over your pubococcygeal muscles, the ones that circle the vagina and that you may involuntary contract in fear of pain upon penetration".

How to do it: The therapist will teach participants the exercise (see handout). She will make sure they understand and will answer their questions. She will recommend that they practice the exercises 10 minutes a day. What steps do they need to take to attain goal of practicing the Kegel exercises everyday? Do they anticipate any potential problems? Can they generate solutions?

Session 5

Review of homework: 1) The therapist will discuss the relaxation exercise; what they liked, what they did not like, the problems encountered and how they are coping with them, etc. What do they need to ensure that they attain their goal of practicing the technique once a day? (e.g. find right time to practice, take phone off hook, etc.). She can suggest that they use the breathing exercises at other times, e.g. before a gynecological exam, before having sex (i.e., help them to generalize this skill). 2) The therapist will discuss dilatation and its effect on pain. How is the partner reacting to these exercises? Have they tried it with his finger? 3) The therapist will discuss the Kegel exercises; any problems? Can they think of solutions? Could these exercises be used before a gynecological exam or before penetration to help prevent muscle contractions? Could these exercises help them generate sexual feelings? (i.e., help them generalize this skill). 4) How did applying arousal techniques work for them and their partners? The therapist can suggest more ways to increase sexual interest if these have not already come up (identifying sexual needs, reading and viewing erotic material, fantasizing, etc.). What might be preventing them from trying out some of the desire and arousal techniques that have been suggested? Why do the things they know about sexual pleasure suddenly become irrelevant when they start to feel the pain?

Approach/avoidance exercise: 1) The therapist will bring up the issue of homework in general and avoidance in particular: what might be preventing them from doing all of the exercises? Could it be linked to them not accepting their pain problem? To some blocks that they are unaware of? To scheduling problems? To intimacy problems? Reemphasize the importance of accepting that they have a recurrent pain problem that will not go away magically. 2) The therapist will ask participants to engage in the following exercise: they should divide a sheet of paper into two columns and list in the first one all the reasons that make them want to do the exercises and in the second column all the reasons that make

them want to avoid doing the exercises. The therapist will ask participants to share what they wrote with the group and problem-solve with them.

Cognitive restructuring. The therapist will begin to help participants to identify thoughts that they say to themselves when they are anticipating pain, using the Pain Diary entries. She will teach them how to replace these anxiety-provoking thoughts by more realistic, relaxing thoughts. She will ask them to start noticing the automatic thoughts that go through their head when they are anticipating pain, when they are experiencing pain, and after an episode of painful intercourse, tell them to write these on paper and to bring the material at the next session. She will suggest that they practice cognitive restructuring before and during the dilatation exercises, as well as when they are engaging in sexual activities with their partners.

Homework. THE THERAPIST GIVES PARTICIPANTS THE COGNITIVE RESTRUCTURING HANDOUT.

1) *Cognitive restructuring*: **Rationale**: The therapist will explain to participants that unrealistic thoughts about pain, such as catastrophization, are linked to higher pain intensity, among other reasons because they provoke anxiety and anxiety is related to increases in pain intensity. These maladaptive thoughts also limit healthy coping and can contribute to maintain unproductive interactions between partners.

How to do it: The therapist will divide the cognitive restructuring into 3 steps that she can list on the blackboard: (a) preparing for the onset of pain: anticipation of pain, (b) confronting and handling the sensations: pain during and after intercourse, (c) handling feelings after an episode of painful intercourse. She will go over the handout with participants and will answer their questions.

2) *Cold application* (e.g. they could use it for pain after intercourse). **Rationale**: The therapist will explain to partcipants that the use of cold often reduces pain intensity and can reduce inflammation to the vulvar area following intercourse.

How to do it: She can suggest they use a bag of frozen vegetables wrapped in a bath cloth and use humor during this discussion.

Session 6

Discussion re: progress and setbacks: The therapist will discuss progress (based on pain ratings, pain diary, etc.) and give positive reinforcement. What are the areas of difficulties? She can also do some problem-solving by discussing what problems they are encountering in general (resistance in themselves, partners, etc.), how to deal with setbacks, etc. and normalize setbacks.

Review of homework: The therapist can review and discuss 1) the dilatation: Have they tried it with their partner yet? Do they have any problems? 2) the Kegel exercises and their effect on vaginal contractions just preceding penetration, as well as their effect on sexual arousal; 3) the arousal and desire suggestions: Have they tried them out? How do they affect their sexual feelings and their pain?

Discussion re: sexual needs and assertiveness. 1) The therapist can use the following questions to guide the discussion: Are there sexual needs clearer? Are they asserting their sexual needs? What difficulties are they encountering with their partners? 2) The therapist will educate participants about what self-assertion is and is not.

Cognitive restructuring. THE THERAPIST GIVES PARTICIPANTS THE COGNITIVE RESTRUCTURING WORKSHEET.

1) The therapist discusses the cognitive restructuring with participants: Did they notice their automatic thoughts? Was there anything special about them? Did they notice a link between their pain level and their automatic thoughts? Did they note their automatic thoughts on paper? The therapist can write some of them on the blackboard. 2) The therapist ractices reframing these thoughts with participants (replacing them with more realistic ones) based on the grid outlined on the worksheet: What steps do they need to take to attain goal of applying the cognitive restructuring? Can they think of any solutions to the problems they are encountering? The therapist should suggest that they practice this as often as possible at home because it represents a skill that they need to master. If they do not practice, they will not acquire mastery and thus the restructuring will not be very effective. 3) The therapist and participants will practice cognitive restructuring as a group, with one generating negative, harmful statements, and the others providing more realistic, pain decreasing statements in return. This can be done in conjunction with the examples on the blackboard.

Homework: 1) *Giving/receiving exercise to do at home*: The therapist will explain the exercise of giving/receiving pleasure (Sensate Focus I), giving both its **rationale** and the details of **how to do it.**

2) The therapist will explain the *use of Xylocaine*, emphasizing the importance of not engaging in more vigorous intercourse (so as to avoid burning due to irritation); she will give each of them their prescription from Dr. Khalifé. Do they foresee any potential problems with the use of Xylocaine?

Session 7

Review of homework. 1) The therapist will discuss the cognitive restructuring: Did they notice any effect on sexual feelings and on pain? Do they feel they master the technique well? What problems are they experiencing? The therapist can do some more on the blackboard if they do not seem to understand it well. 2) The therapist will continue the arousal and desire discussion, the review of exercises and problems, etc. 3) She will discuss the Kegel and dilatation exercises: How is it different with their partners compared to when they are alone? 4) She will also discuss the application of Xylocaine: Did any of them try it? What are the advantages and disadvantages of using Xylocaine? If it is causing them more pain, they should stop using it. Did they notice any effects on their sexual feelings or their pain?

Discussion re: asserting oneself with partner. The therapist will discuss problems participants might be encountering with their partners re: pain and sex (or problems they are afraid of encountering with a new partner if they do not presently have one). She will discuss assertiveness and communication with partner. She can have them think of one area of difficulty (e.g. initiation, arousal problems, asserting sexual needs, broaching the topic of sex, taking partners' frustration too personally, etc.) and discuss reasons why it is difficult for them to talk about certain of these issues with their partners, what are the blocks, etc. It can be useful to do some cognitive restructuring with them re: some of these issues (mostly, have members of the group do it), reframe problems, etc. The therapist should teach them basic communication skills such as how to say something, when to say it, speaking from the "I" and stating one's feelings as opposed to blaming their partner, etc. She can discuss the disadvantages of not saying what is on their mind (e.g. if they say to their partner two years down the road that they do not enjoy some

sexual behavior he has had all along, the partner may be more upset than if they say it the first or second time he does it).

Communication exercise. In the context of the above discussion, the therapist will ask participants to separate a sheet of paper into two columns and to list on one side what they believe to be their communications strengths and on the other side what they believe to be the communication difficulties or weaknesses that they wish to improve on. The therapist will ask the participants to share some of the information on their list with other members of the group.

Homework. THE THERAPIST GIVES PARTICIPANTS THE LIST OF COPING SELF-STATEMENTS HANDOUT.

How to do it: She goes over it with them and gives them examples of situations in which they could use these self-statements. The **rationale** is the same as for cognitive restructuring.

Session 8

Review of what has been learned. The therapist will review with participants what has been learned: Do they feel they have integrated what they learned into their regular lifestyle? What will they do in the future if they experience a period of increased pain, a flare-up?

Review exercise. The therapist will have participants write down the progress they made and the issues that are still problematic. She will ask them to share some of what they wrote with the rest of the group. How do they plan to work on these issues?

Generalization of progress. 1) The therapist will lead this discussion by asking some of the following questions: How can they ensure that they keep practicing what they have learned? What problems do they anticipate? What might help prevent these problems? 2) She will discuss with them how to deal with doctors in the future (self-assertion, etc.).

Anonymous evaluation of treatment. 1) The therapist will ask participants to write on paper (anonymously) the strengths and weaknesses of this treatment. 2) The therapist can use some of the following questions to discuss some of the issues they wrote on paper. Was there anything they would have wanted to discuss or learn in the group but did not? How could this treatment be improved?

Study-related issues. 1) The therapist will inform participants that Janet Bradley will be calling them or has already called them re: their post-treatment assessment. She will call them for their 6-month follow-up assessment in 6 months. 2) She will remind them that they can consult Dr. Khalifé or Dr. Pagidas even once the study is over, for support, etc. and that they can also stay in touch with Janet Bradley after the study is over.

Tools for the future. 1) The therapist will give participants brochures from the Vulvar Pain Foundation and from the National Vulvodynia Association. 2) She will suggest the following books: 1) Lonnie Barbach, "For yourself", 2) Lonnie Barbach, "For each other", 3) Margaret Caudill, "Managing pain before it manages you", and any other book on sexuality that seems serious and instructive.

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Pain management
Treatment plan

Session 1

Introductions (therapist and participants)

Explanation of the treatment plan and of the basic elements of the pain management program

Education and discussion re: vulvar vestibulitis syndrome

Education and discussion re: the phenomenon of pain

Home Exercise: Localization of pain

Home Exercise: Pain Diary

Questionnaire: Expectations toward treatment

Pain questionnaires

Distribution of Daily Pain Rating forms

Copy of signed consent

Session 2

Question period re: VVS article

Discussion re: pain diary and pain localization exercise

Desensitization exercise: video

Discussion: a different view of pain

Home Exercise: breathing

Session 3

Review of mirror/drawing exercise

Discussion re: pain diary. Impact of pain on thoughts, emotions, and behaviors

Discussion re: avoidance of sexual activities and role of partner

Discussion re: means that can be used to increase desire

Discussion re: breathing exercises

Group and Home Exercise: deep breathing

Home Exercise: vaginal dilatation

Session 4

Discussion re: breathing and dilatation exercises: problems, solutions

Discussion re: the different ways to incorporate the means to increase desire into one's sex life: problems, solutions

Discussion re: how to increase arousal
Home exercise: relaxation
Home Exercises: series of contractions-release of the vaginal muscles (Kegel exercises)

Session 5

Discussion re: breathing and dilatation exercises: impact on pain
Discussion re: Kegel exercises: problems, solutions, when to use them
Discussion re: the application of various means to increase desire and arousal: impact on pain
Discussion re: relaxation: impact on pain
Exercise to do in therapy: approach/avoidance
Cognitive restructuring: begin to identify automatic thoughts during the anticipation of pain, the experience of pain and after having experienced pain
Home Exercise: note automatic thoughts on paper
Explanation of the use of ice in the relief of pain after intercourse

Session 6

Discussion re: progress and setbacks: problem-solving
Discussion re: desire, arousal, breathing, dilatation, and Kegel exercises
Home exercise: giving-receiving
Discussion re: sexual needs and sexual assertiveness
Cognitive restructuring: learning techniques aimed at replacing unrealistic automatic thoughts
by more realistic ones
a) anticipation of pain
b) confronting pain sensations during penetration
c) emotions and thoughts following a pain episode
Explanation of the use of an anesthetic gel to relieve pain during intercourse

Session 7

Cognitive restructuring: problems, solutions
Discussion re: desire and arousal
Discussion re: dilatation and Kegel exercises: is it different with their partners?
Discussion re: asserting oneself with partner
Exercise to do in therapy: communication strengths and weaknesses
Discussion re: use of ice and of anesthetic gel

Tool: list of self-statements

Session 8

Revision of what has been learned: write list of accomplished progress, discussion

Revision of difficulties and of things that have not changed: acceptance, tools, other resources

Discussion re: 6-month follow-up period: how to continue practicing what has been learned, how to continue progressing

Anonymous evaluation of treatment

Book recommendations

Gestion de la douleur
Plan de traitement

Séance 1

Présentations (thérapeute et participantes)
Explication du plan de traitement et des éléments de base du programme de gestion de la douleur
Éducation et discussion portant sur la vestibulite vulvaire
Éducation et discussion portant sur le phénomène de la douleur
Exercice à faire chez soi: localisation de la douleur
Exercice à faire chez soi: journal de douleur
Questionnaire: Attentes vis-à-vis du traitement
Questionnaires sur la douleur
Inventaires quotidiens de la douleur
Copie du formulaire de consentement signé

Séance 2

Questions concernant l'article portant sur la vestibulite vulvaire
Discussion portant sur les exercices de localisation de la douleur et le journal de douleur
Exercice de désensibilisation: vidéo
Discussion portant sur une nouvelle vision de la douleur
Exercice à faire chez soi: respiration

Session 3

Revision de l'exercice de localisation de la douleur: miroir et dessin
Discussion portant sur l'exercice du journal de la douleur. Impact des pensées, émotions, sensations physiques et comportements sur la douleur et vice versa
Discussion portant sur l'évitement des activités sexuelles et le rôle du partenaire
Discussion portant sur les moyens qui peuvent être utilisés afin d'augmenter le désir sexuel
Exercice à faire chez soi et en groupe: respiration profonde
Exercice à faire chez soi: dilatation vaginale

Séance 4

Discussion portant sur les exercices de respiration et de dilatation: problèmes, solutions

Discussion portant sur les différentes façons d'incorporer à sa vie sexuelle des moyens visant à augmenter le désir sexuel: problèmes, solutions
Discussion portant sur les moyens qui peuvent être utilisés afin d'augmenter l'excitation sexuelle
Exercice à faire chez soi: relaxation
Exercices à faire chez soi: série de contractions-relâchements des muscles du vagin (exercices Kegel)

Séance 5

Discussion portant sur les exercices de respiration et de dilatation: impact sur la douleur
Discussion portant sur les exercices Kegel: problèmes, solutions, quand les utiliser
Discussion portant sur l'application de divers moyens visant à augmenter le désir et l'excitations sexuelle: impact sur la douleur
Discussion portant sur la relaxation: impact sur la douleur
Exercice à faire pendant la séance: approche/évitement
Restructuration cognitive: commencer à identifier ses pensées automatiques lors de l'anticipation de la douleur, lors de l'expérience de la douleur, et après avoir ressenti de la douleur
Exercice à faire chez soi: noter sur papier ses pensées automatiques
Explication de l'utilisation de la glace pour soulager la douleur après les relations sexuelles

Séance 6

Discussion portant sur le progrès et les dfficultés: résolution de problème
Discussion portant sur les exercices visant à stimuler le désir et l'excitation, la respiration, les exercices Kegel et la dilatation
Exercice à faire chez soi avec le partenaire: donner-recevoir
Discussion portant sur les besoins sexuels et l'affirmation de sa sexualité
Restructuration cognitive: apprentissage de techniques visant à remplacer les pensées automatiques irréalistes et nuisibles par des pensées plus réalistes
a) anticipation de la douleur
b) confronter les sensations de douleur pendant la pénétration
c) émotions et pensées suite à un épisode de douleur
Explication de l'usage d'un gel anesthésiant pour soulager la coïtalgie

Séance 7

Restructuration cognitive: problèmes, solutions
Discussion portant sur l'excitation et le désir
Discussion portant sur les exercices de dilatation et les exercices de Kegel: est-ce différent avec leurs partenaires?
Discussion: s'affirmer vis-à-vis son partenaire sexuel.
Exercice à faire pendant la séance: savoir communiquer: forces et faiblesses
Discussion portant sur l'utilisation de la glace et du gel anesthésiant
Outil: liste d'affirmations à se dire à soi-même.

Séance 8
Revision des apprentissages: écrire liste des progrès accomplis, discussion
Revision des difficultés et des choses qui n'ont pas changé: acceptation, outils, autres ressources
Discussion portant sur la période de 6 mois de suivi: comment continuer à mettre en pratique ce qui a été appris; comment continuer à progresser
Évaluation anonyme du traitement
Recommendation de livres qui aideront à poursuivre le travail entrepris

Pain Diary

To fill out after engaging in an activity that caused pain (e.g. intercourse, finger insertion, etc.). The items in italics (11, 12, 13, 14, 15) refer only to pain experienced during sexual activities.

Name: _____ Date: _____

1. Day: _____ 2. Time: _____
3. Time of menstrual cycle _____ 4. Pain intensity (0 to 10): _____
5. Cause of the pain _____ 6. Duration of the pain: _____
7. Where were you? _____
8. What were you feeling and thinking just prior to the pain ?_____

_____

9. What were you feeling and thinking during the pain? _____

_____

10. What were you feeling and thinking after the pain? _____

_____

11. How much time did you spend on sex play? _____
*12. How aroused were you (0 to 10)?*_____
*13. How lubricated were you (0 to 10)?*_____
14. Up to what point were you in the mood for sex (0 to 10)? _____
15. What was your partner's reaction to your pain? _____

_____

16. How relaxed did you feel (0 à 10)? _____
17. What did you do to try to reduce the pain? _____

_____

18. How effective was this? (Circle the appropriate number).

0 = did not help at all 1 = helped very little 2 = helped somewhat
3 = helped a lot 4 = stopped the pain

Additional comments:

_____

_____

_____

Journal de douleur

Remplir **immédiatement** après avoir fait une activité ayant causé de la douleur (ex.: relation sexuelle avec pénétration, insertion de doigt(s), etc.). Les questions en italique (11, 12, 13, 14, 15) se rapportent seulement à la douleur ressentie lors d'activités sexuelles.

Nom: _____ Date: _____

1. Jour : _____ 2.Heure: _____
3. Moment du cycle menstruel: _____ 4. Intensité de la douleur (0 à 10): _
5. Cause de la douleur: _____ 6. Durée de la douleur: _____
7. Où étiez-vous? _____
8. Que ressentiez-vous et à quoi pensiez-vous précédant la douleur?_____

_____

9. Que ressentiez-vous et à quoi pensiez-vous en pendant la douleur? _____

_____

10. Que ressentiez-vous et à quoi pensiez-vous après la douleur? _____

_____

11. Combien de temps avez-vous consacré aux jeux préléminaires? _____
*12. Jusqu'à quel point étiez-vous excitée (0 à 10)?*_____
*13. Jusqu'à quel point étiez-vous lubrifiée (0 à 10)?*_____
14. Jusqu'à quel point aviez-vous envie d'avoir une relation sexuelle (0 à 10)? _____
15. Comment votre partenaire a-t-il réagi à la douleur? _____
16. Jusqu'à quel point vous sentiez-vous détendue (0 à 10)? _____
17. Qu'avez-vous fait pour diminuer la douleur? _____

_____

18. Jusqu'à quel point cela a-t-il été efficace? (Encerclez la réponse appropriée).

0 = n'a pas du tout aidé 1 = a très peu aidé 2 = a quelque peu aidé
3 = a beaucoup aidé 4 = a arrêté la douleur

Commentaires additionnels:

_____

_____

_____

_____

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Session 1

Prepare a file in which you will keep all the material used in the pain management group. Always bring your file to each of the group meetings.

Exercise 1: Pain diary

The Pain diary constitutes a tool that will help you better understand your pain and the factors that influence it. The diary will also help you measure your progress in the weeks to come. We will use the Pain diary regularly in our group discussions.

Fill in a Pain diary form **immediately** following each event having caused you pain.

Answer all the questions, except those that don't relate to the activity you just engaged in. For example, certain questions only pertain to sexual activities, thus if you fill out a Pain diary form following a non-sexual activity, ignore those questions.

Exercise 2: Localization of the pain

During the group session, we have identified where the pain is located on the model. Now, it's your turn to identify where the pain is located on yourself.

Necessary material: mirror, sheet of paper, crayon or pen.

Choose a moment during which you know you will not be disturbed. If necessary, unplug the phone or leave the answering machine on. To feel more at ease, you can also choose a room where you can lock the door. If the idea of doing this exercise makes you a bit nervous, take a bath before starting, or engage in another activity that usually helps you to relax.

Observe your genitals attentively, using the mirror. Touch different points to see where the pain is located. Make a drawing of your genitals, and indicate on the drawing where the pain is located. Artistic talent doesn't matter! What counts is being able to localize the pain, i.e., to know exactly where it hurts and where it doesn't hurt.

If you try the exercise once and find that it's not working out (e.g. you're feeling uncomfortable, etc.), repeat it a second time, a third time, etc., until you feel relatively at ease and are able to make a drawing of your genitals.

While observing your genitals, note your reactions on the back of the sheet on which you did the drawing. Write everything that goes through your head, without censuring yourself. For example, you may experience certain reactions towards the appearance of your genitals, their smell, etc.

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Exercices à faire chez soi
Séance 1

Préparez-vous un fichier dans lequel vous conserverez tout le matériel utilisé lors de l'atelier de gestion de la douleur. Apportez toujours votre fichier à chacune des rencontres de groupe.

Exercice 1: Journal de douleur

Le Journal de douleur constitue un outil qui vous aidera à mieux comprendre votre douleur et les facteurs qui l'influencent. Le Journal vous aidera aussi à mesurer votre progrès au fil des semaines. Nous nous servirons régulièrement du Journal de douleur lors de nos discussions de groupe.

Remplissez un exemplaire du Journal de douleur **immédiatement** après chaque événement ayant suscité de la douleur.

Répondez à toutes les questions, sauf celles qui ne se rapportent pas à l'activité que vous venez de faire. Par exemple, certaines questions se rapportent uniquement à une relation sexuelle, donc si vous remplissez votre journal de douleur suivant une activité non-sexuelle, ignorez ces questions.

Exercice 2: Localisation de la douleur

En groupe, nous avons identifié où se situe la douleur sur le modèle. Maintenant, c'est à votre tour d'identifier la douleur sur vous-mêmes.

Matériel nécessaire: miroir, feuille de papier, crayon ou stylo.

Choisissez un moment lors duquel vous savez que vous ne serez pas dérangée. Si nécessaire, décrochez le téléphone ou branchez le répondeur téléphonique. Pour vous sentir plus à l'aise, vous pouvez également vous installer dans un endroit où vous pourrez verrouiller la porte. Si l'idée de faire cet exercice vous rend un peu nerveuse, prenez un bain avant de commencer, ou faites une autre activité qui vous détend habituellement.

Observez vos organes génitaux attentivement, à l'aide du miroir. Touchez à différents endroits pour voir où se situe la douleur. Faites un dessin de vos organes génitaux, et montrez sur le dessin où se situe la douleur pour vous. Le talent artistique importe peu! Ce qui compte, c'est que vous arriviez à localiser la douleur, à savoir exactement où ça fait mal, et où ça ne fait pas mal.

Si vous essayez l'exercice une première fois et que ça ne se passe pas bien (ex.: vous vous sentez trop mal à l'aise, etc.), répétez-le une seconde fois, une troisième fois, etc., jusqu'à ce que vous vous sentiez relativement à l'aise et que vous arriviez à faire un dessin.

En observant vos organes génitaux, notez vos réactions à l'endos de la feuille sur laquelle vous faites votre dessin. Ecrivez tout ce qui vous passe par la tête, sans vous censurer. Par exemple, vous avez peut-être des réactions vis-à-vis l'apparence de vos organes génitaux, leur odeur, etc.

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Session 3

Exercise 3: Deep breathing

Choose a moment during which you know you will not be disturbed. If necessary, unplug the phone or leave the answering machine on. To feel more at ease, you can also choose a room where you can lock the door. If the idea of doing this exercise makes you a bit nervous, take a bath before starting, or engage in another activity that usually helps you to relax.

1. Lie down on your back or in a comfortable chair or sofa.
2. Take short and deep breaths, maintaining the air in your lungs after each one. Go slowly; take your time.
3. Keep the air in your lungs for a couple of seconds, and then slowly exhale, slightly opening your mouth. While exhaling, notice the sensation of calm and relaxation that you are bringing forth with this type of breathing.
4. You can increase the relaxation effect by concentrating on words like "calm", "peacefulness", and "relaxation" while exhaling.
5. Repeat the exercise 10 consecutive times.
6. Repeat this sequence of 10 breaths once a day or more.

If intruding thoughts or worries cross your mind, imagine that your mind is a sieve and that all the thoughts just pass through its holes. Don't hang on to your thoughts.

Exercise 4: Dilatation

Choose a moment during which you know you will not be disturbed. If necessary, unplug the phone or leave the answering machine on. To feel more at ease, you can also choose a room where you can lock the door. If the idea of doing this exercise makes you a bit nervous, take a bath before starting, or engage in another activity that usually helps you to relax.

Practice **one dilatation exercise per day**. The sequence of exercises on the following page will serve as a model, although you will not always necessarily follow it precisely.

As is evident by the sequence and the fact that you must do one exercise a day, you will often repeat the same exercise two or three days in a row, which will enable you to master it well. When you feel that you have mastered a given exercise, go on to the next one. You may progress slower or faster than the model sequence. Go at your own pace, making sure that you practice one exercise a day.

First, do the breathing exercise described above. Then do a dilatation exercise, starting with exercise 1 (insertion of your smallest finger). Once you have succeeded in inserting the finger, keep it inserted for about 5 minutes, continuing to take deep breaths. You might not succeed right away. If you can't insert your finger, just touch the entry of your vagina with the tip of the finger. You can try inserting it farther the next time you do the exercise. Observe how you're feeling (anxious, frustrated, etc.). Don't hang on to those emotions; concentrate on your breathing. If you feel pain during the exercise, note it in the Pain Journal, just as for any other activity.

Gradation of dilatation exercises

1. insert smallest finger alone	Session 3
2. insert second smallest finger alone	Session 3
3. insert third smallest finger alone	Session 3
4. insert index or middle finger and move around gently	Session 4
5. insert partner's smallest finger themselves	Session 4
6. insert partner's index themselves	Session 4
7. have partner insert his index	Session 4
8. insert 2 of their own fingers alone	Session 5
9. have partner insert his index and move around gently	Session 5
10. have partner insert 2 fingers	Session 6
11. insert 2 fingers alone and move around gently	Session 6
12. have partner insert 2 fingers and move around gently	Session 6
13. insert penis themselves with no thrusting	Session 7
14. have partner insert penis with no thrusting	Session 7
15. attempt gentle thrusting, teaching partner what kind of thrusting hurts less	Session 7

Directives
Exercices à faire chez soi
Séance 3

Exercice 3: Respiration profonde

Choisissez un moment lors duquel vous savez que vous ne serez pas dérangée. Si nécessaire, décrochez le téléphone ou branchez le répondeur téléphonique. Pour vous sentir plus à l'aise, vous pouvez également vous installer dans un endroit où vous pourrez verrouiller la porte.

1. Étendez-vous sur le dos ou asseyez-vous dans un fauteuil confortable.
2. Prenez de courtes et profondes inspirations, en maintenant l'air dans vos poumons après chacune des inspirations. Allez-y lentement.
3. Maintenez l'air dans vos poumons pour quelques secondes, et expirez lentement, en ouvrant légèrement la bouche. En expirant, prenez conscience de la sensation de calme et de relaxation que vous venez de faire apparaître avec ce genre de respiration.
4. Vous pouvez augmenter l'effet de détente en vous concentrant sur des mots tels "calme", "détente", et "relaxation" lors de l'expiration.
5. Répétez cet exercice 10 fois consécutives.
6. Répétez la séquence de 10 respirations 1 fois par jour.

Si des préoccupations ou des inquiétudes traversent votre esprit, imaginez que votre esprit est une passoire et que toutes les pensées qui vous déconcentrent traversent les trous de la passoire. Ne vous accrochez pas à vos pensées.

Exercice 4: Dilatation

Choisissez un moment lors duquel vous savez que vous ne serez pas dérangée. Si nécessaire, décrochez le téléphone ou branchez le répondeur téléphonique. Pour vous sentir plus à l'aise, vous pouvez également vous installer dans un endroit où vous pourrez verrouiller la porte.

Pratiquez **un exercice de dilatation par jour**. La séquence ci-dessous vous servira de modèle, quoique vous ne la suivrez pas nécessairement à la lettre. Comme vous pouvez le constater, vous allez souvent répéter le même exercice deux ou trois jours de

suite, ce qui vous permettra de bien le maîtriser. Quand vous sentez que vous maîtrisez bien un des exercices, passez au suivant. Il est possible que vous progressiez plus lentement ou plus rapidement que la séquence de progression ci-dessous. Allez à votre rythme, en vous assurant de pratiquer un exercice par jour.

En premier lieu, faites l'exercice de respiration profonde décrit ci-haut. Faites ensuite un exercice de dilatation, en commençant par l'exercice 1 (insertion du petit doigt). Lorsque vous avez réussi à insérer le doigt, gardez-le ainsi pendant environ 5 minutes, en continuant de prendre des respirations profondes. Il est possible que vous n'arriviez pas à insérer votre doigt. Si c'est le cas, touchez seulement l'entrée de votre vagin avec votre doigt. Vous pourrez essayer de l'insérer la prochaine fois que vous pratiquerez l'exercice. Observez comment vous vous sentez (anxieuse, frustrée, etc.). Ne vous accrochez pas à ces émotions; concentrez-vous plutôt sur votre respiration. Si vous ressentez de la douleur en faisant l'exercice, notez-le dans votre Journal de Douleur, comme vou le feriez pour n'importe quelle autre activité.

<u>Séquence des exercices de dilatation</u>

1. insérez votre petit doigt	Séance 3
2. insérez doigt just un peu plus gros que petit doigt	Séance 3
3. insérez doigt du milieur (majeur)	Séance 3
4. insérez index ou majeur et bougez le doigt en douceur	Séance 4
5. insérez vous-mêmes le petit doigt de votre partenaire	Séance 4
6. insérez vous-même l'index de votre partenaire	Séance 4
7. demandez à votre partenaire d'insérer son index	Séance 4
8. insérez 2 de vos doigts	Séance 5
9. demandez à votre partenaire d'insérer son index et de bouger doucement	Séance 5
10. demandez à votre partenaire d'insérer 2 doigts	Séance 6
11. insérez 2 de vos doigts et bougez doucement	Séance 6
12. demandez à votre partenaire d'insérer 2 doigts et de bouger doucement	Séance 6
13. insérez vous-même le pénis de votre partenaire sans va-et-vient	Séance 7
14. demandez à votre partenaire d'insérer son pénis sans va-et-vient	Séance 7
15. essayez un mouvement de va-et-vient en douceur, indiquant à votre partenaire quel type de va-et-vient vous préférez	Séance 7

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Session 4

Exercise 5: Relaxation

Choose a moment during which you know you will not be disturbed. If necessary, unplug the phone or leave the answering machine on. To feel more at ease, you can also choose a room where you can lock the door. If the idea of doing this exercise makes you a bit nervous, take a bath before starting, or engage in another activity that usually helps you to relax.

1. Sit in a comfortable chair, keeping a good posture (back straight, etc.).
2. Close your eyes and breath regularly, breathing from the abdomen rather than from the chest.
3. Once you are successfully breathing from your abdomen, start counting your breaths from 1 to 10, counting on the exhale. For example, breath in once, and on the exhale, count 1 in your head. Inhale again, and on the exhale, count 2 in your head, and continue this way until 10. When you reach the number 10, start again at 1.
4. Concentrate only on your breathing and your counting. You will notice that your mind naturally wanders away from these two elements and that all sorts of unrelated thoughts will go through your head. When this occurs, simply bring back your mind to the breathing and the counting. If you lose your count, start again at 1.
5. **Practice this exercise for 10 minutes the first week, and for 15 minutes the following weeks.** You can place your watch near you and open your eyes periodically to see where you're at. Soon enough you won't be needing your watch and will know pretty much when to stop.
6. Repeat the sequence of 10 or 15 minutes once a day.

If intruding thoughts or worries cross your mind, imagine that your mind is a sieve and that all the thoughts just pass through its holes. Don't hang on to your thoughts.

Exercise 5: Kegel

The goal of Kegel exercises is to increase your control over the muscles of the vagina so that you can relax them completely during intercourse and this, despite of the pain. When you involuntarily contract those muscles, it contributes to increase the intensity of the pain. It is thus very important to learn to relax those muscles.

To make contact with your vaginal muscles, try stopping the flow of urine the next time you'll go to the washroom. The muscles that will enable you to do this are the muscles that circle your vagina and urethra; these muscles are the ones you'll be working on during the Kegel exercises.

Choose a moment during which you know you will not be disturbed. If necessary, unplug the phone or leave the answering machine on. To feel more at ease, you can also choose a room where you can lock the door. If the idea of doing this exercise makes you a bit nervous, take a bath before starting, or engage in another activity that usually helps you to relax.

Kegel exercises are easy to do. Start by contracting your vaginal muscles, and keep the contraction for 10 seconds (count the seconds if you don't have an appropriate watch). Then relax the muscles for the following 10 seconds. Contract the muscles again and maintain the contraction for 10 seconds, then relax for 10 seconds, and keep alternating this way between the contraction and the relaxation up to a **sequence of 10 contractions-10 relaxations**.

Practice **one sequence of Kegel exercises per day**.

First, do the relaxation exercise described above, or a deep breathing exercise. Then do a sequence of Kegel exercises. If you feel pain during the exercise, note it in the Pain Journal, just as for any other activity.

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Séance 4

Exercice 5: Relaxation

Choisissez un moment lors duquel vous savez que vous ne serez pas dérangée. Si nécessaire, décrochez le téléphone ou branchez le répondeur téléphonique. Pour vous sentir plus à l'aise, vous pouvez également vous installer dans un endroit où vous pourrez verrouiller la porte.

1. Asseyez-vous dans un fauteuil confortable, en prenant soin d'avoir une bonne posture.
2. Fermez les yeux, et prenez des respirations régulières, en respirant par le ventre plutôt que par la poitrine.
3. Lorsque vous respirez bien par le ventre, commencez à compter vos respirations de 1 à 10, en comptant sur l'expiration. Par exemple, vous inspirez une première fois, et sur l'expiration, vous comptez 1 dans votre tête. Vous inspirez une seconde fois, et sur l'expiration, vous comptez 2 dans votre tête, ainsi de suite jusqu'à 10. Lorsque vous avez atteint le chiffre 10, vous recommencez à 1.
4. Concentrez-vous uniquement sur votre respiration et sur le comptage. Vous allez constater que votre esprit s'éloigne naturellement de ces deux éléments et que toutes sortes d'autres choses vous passent par la tête. Lorsque cela se produit, ramenez simplement votre esprit à votre respiration et au comptage. Si vous perdez le compte, recommencez à 1.
5. **Pratiquez cet exercice pendant environ 10 minutes la première semaine, et passez à 15 minutes la semaine suivante.** Vous pouvez placez votre montre près de vous et vous ouvrir les yeux de temps à autre pour voir où vous en êtes. Très bientôt, vous n'aurez plus besoin de la montre et saurez à peu près quand arrêter.
6. Répétez la séquence de 10 ou 15 minutes 1 fois par jour.

Si des préoccupations ou des inquiétudes traversent votre esprit, imaginez que votre esprit est une passoire et que toutes les pensées qui vous déconcentrent traversent les trous de la passoire. Ne vous accrochez pas à vos pensées.

Exercice 5: Kegel

Les exercices de Kegel visent à augmenter votre contrôle sur les muscles de votre vagin afin de pouvoir les détendre complètement lors de la pénétration, et ce malgré la douleur. Lorsque vous les contractez sans vous en rendre compte, ceci augmente la sensation de douleur. Il est donc très important d'apprendre à relâcher ces muscles.

Afin de prendre contact avec les muslces de votre vagin, essayez d'arrêter le flot d'urine la prochaine fois que vous irez à la toilette. Les muscles qui vous permettront de le faire sont les muscles qui entourent votre vagin ainsi que votre urètre; ce sont ces muslces que vous allez travailler lors des exercices de Kegel.

Choisissez un moment lors duquel vous savez que vous ne serez pas dérangée. Si nécessaire, décrochez le téléphone ou branchez le répondeur téléphonique. Pour vous sentir plus à l'aise, vous pouvez également vous installer dans un endroit où vous pourrez verrouiller la porte.

Les exercices de Kegel sont simples à faire. Commencez par contracter vos muscles du vagin, et gardez la contraction pendant 10 secondes (comptez les secondes si vous n'avez pas de montre appropriée). Ensuite relâchez vos muscles pendant les prochaines 10 secondes. Recommencez la contraction et maintenez-la pendant 10 secondes, puis relâchez pendant 10 secondes, et ainsi de suite, pour une **séquence de 10 contractions-10 relâchements**.

Pratiquez **une séquence d'exercices de Kegel par jour**.

En premier lieu, faites l'exercice de relaxation décrit ci-haut ou un exercice de respiration profonde. Faites ensuite une séquence d'exercices de Kegel. Si vous ressentez de la douleur en faisant l'exercice, notez-le dans votre Journal de Douleur, comme vous le feriez pour n'importe quelle autre activité.

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Session 5

Exercise 7: Cognitive Restructuring

Our thoughts have a direct impact on the way we perceive and react to events that happen in our lives. The means we use to cope with a given problem contribute in fact to modify our perception of that problem. For example, the way you react to your pain has a direct effect on how you perceive this pain. Thus, certain ways of reacting are more constructive than others in that they enable you to experience less pain. Cognitive restructuring is a technique whose goal is to help you to cope more efficiently with the pain, thus enabling you to perceive it as less intense. When you experience pain, certain thoughts come automatically to mind, and this at three important points in time:

1) when you're anticipating pain
2) when you're experiencing pain
3) after a pain episode

Cognitive restructuring is a technique that you can use to learn to cope with the above phases of the pain experience. This technique will help you to react differently to your pain.

This week, pay attention to the automatic thoughts that will come to mind during the three phases mentioned above. Note them on paper and bring them to the next session. Try to replace them by more realistic thoughts based on our discussion of session 5.

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Séance 5

Exercice 7: Restructuration cognitive

Nos pensées ont un impact direct sur notre façon de percevoir et de réagir aux événements. Les moyens que nous utilisons pour faire face à un problème donné contribuent en fait à modifier notre perception du problème. Par exemple, votre façon de réagir à la douleur a un effet direct sur votre perception de cette douleur. Ainsi, certaines façons de réagir sont plus constructives que d'autres en ce sens qu'elles permettent de ressentir moins de douleur. La restructuration cognitive est une technique dont le but est de vous aider à mieux composer avec le douleur, et ainsi, de vous permettre de la percevoir d'une façon moins intense.
Lorsque vous ressentez de la douleur, certaines pensées vous viennent automatiquement à l'esprit, et ce à trois moments importants:

1) lorsque vous anticipez la douleur
2) lorsque vous ressentez de la douleur
3) après avoir ressenti de la douleur

La restructuration cognitive est une technique que vous pouvez utiliser afin de mieux composer avec ces différentes étapes de la douleur. Cette technique vous permettra de réagir à votre douleur différemment.

Cette semaine, portez attention aux pensées automatiques que vous aurez pendant les trois étapes ci-haut mentionnées. Notez-les sur papier et apportez-les à la prochaine séance. Essayer de les remplacer par des pensées plus réalistes en vous basant sur notre discussion de la séance 5.

Coping self-statements

The goal of these self-statements is to help you develop an active rather than a passive attitude towards your pain problem. When the pain appears, try to think of a plan that incorporates various tools that we have discussed together. Develop your plan from the very beginning of the pain experience; don't wait until the pain becomes unbearable. It's easier to maintain control of the situation when the pain is not too intense. Use the following coping self-statements as needed.

1. STOP worrying. Worrying won't help the pain. What are some of the helpful things I can do instead?

2. I'm feeling anxious. I'm afraid that the pain may increase. That's natural. But that's no reason to give up. Let me just breathe deeply and relax.

3. I'm feeling tense. That lets me know that I should take some slow, deep breaths and concentrate on relaxing thoughts.

4. I won't get overwhelmed. I'll just take one step at a time.

5. I have a lot of pain right now. Rather than letting the pain take control of my body and my sex life, I will try to reduce it by concentrating on arousing fantasies and by breathing deeply.

6. STOP these negative thoughts. Let me just concentrate on one of the strategies that will help me cope with the pain.

Affirmations

L'objectif de ces affirmations est de vous aider à développer une attitude active plutôt que passive face à votre problème de douleur. Quand la douleur apparaît, essayer de penser à un plan d'action incorporant différents outils dont nous avons discuté ensemble. Développez votre plan d'action dès le début de la douleur; n'attendez pas qu'elle soit insoutenable. Il est plus facile de garder le contrôle de la situation quand la douleur n'est pas trop intense. Utilisez les affirmations ci-dessous au besoin.

1. ARRETE de t'inquiéter. S'inquiéter n'aide pas la douleur. Quelles sont les outils que je pourrais utiliser maintenant plutôt que de m'inquiéter?

2. Je me sens anxieuse. J'ai peur que la douleur s'intensifie. C'est normal. Mais ce n'est pas une raison pour abandonner. Je vais essayer de respirer profondément et de me détendre.

3. Je me sens tendue. Ceci m'indique que je devrais porter attention à ma respiration et me concentrer sur des pensées relaxantes.

4. Je ne me laisserai pas dépasser par les événements. Je vais y aller une étape à la fois.

5. J'ai beaucoup de douleur présentement. Plutôt que de laisser la douleur prendre contrôle de mon corps et de ma relation sexuelle, je vais essayer de la réduire en me concentrant sur des images qui me procurent de l'excitation sexuelle et en respirant.

6. ARRETE ces pensées négatives. Concentre-toi sur les stratégies qui t'aideront à réduire la douleur.

Appendix 17 - Participant Compliance Form

GCBT

Randomized Treatment Outcome Study

Compliance form

Pain management

Please fill out this form every week or every two weeks, depending on where we're at in the schedule. Give back this compliance form to your therapist at every session. Certain exercises will not have been covered yet in the group at the time when you will be filling out the form. Fill out the form only for the exercises that have already been covered. Please be as honest as possible; your compliance with the exercises will not be discussed in the group. We need to know how you comply with the exercises in order to evaluate the overall effectiveness of a the treatment.

Patient #: _____ Last session #: _____

Name of therapist: _____

I practiced the breathing exercises _____ times _____this week _____ these last 2 weeks.

I practiced the dilatation exercises _____ times _____this week _____ these last 2 weeks.

I practiced the relaxation exercises _____ times _____this week _____ these last 2 weeks.

I practiced the Kegel exercises _____ times _____this week _____ these last 2 weeks.

I tried the Xylocaine _____ times _____this week _____ these last 2 weeks.

I tried cold application _____ times _____this week _____ these last 2 weeks.

I practiced cognitive restructuring exercises _____ times _____this week _____ these last 2 weeks.

I practiced desire exercises _____ times _____this week _____ these last 2 weeks.

I practiced arousal exercises _____ times _____this week _____ these last 2 weeks.

I used my list of coping self-statements _____ times _____this week _____ these last 2 weeks.

Formulaire d'adhésion au traitement

Gestion de la douleur

Veuillez remplir ce formulaire à chaque semaine ou à chaque deux semaines, dépendant d'où nous en sommes dans l'horaire des séances. Certains exercices n'auront pas encore été couverts au moment où vous remplirez le formulaire. Remplissez le formulaire seulement pour les exercices ayant déjà été discutés dans le groupe. Retournez votre formulaire au thérapeute à chaque semaine. Essayez d'être le plus honnête possible lorsque vous remplissez le formulaire; votre adhérence au traitement ne sera pas discutée dans le groupe. Nous avons besoin de savoir si vous faites ou non les exercices afin d'évaluer l'efficacité du traitement.

Numéro de sujet: _____ Numéro de dernière séance: _____

Nom du thérapeute: _____

J'ai pratiqué les exercices de respiration _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai pratiqué les exercices de dilatation _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai pratiqué les exercices de relaxation _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai pratiqué les exercices de Kegel _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai essayé le gel Xylocaine _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai essayé l'application de froid _____ times _____this week _____ these last 2 weeks .

J'ai pratiqué la restructuration cognitive _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai pratiqué les exercices de désir sexuel _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai pratiqué les exercices d'excitation sexuelle _____ fois _____cette semaine _____ ces deux dernières semaines.

J'ai utilisé ma liste d'affirmations _____ fois _____cette semaine _____ ces deux dernières semaines.

Appendix 18 - sEMG Biofeedback Protocol

Randomized Treatment Outcome Study

Biofeedback protocol

Do not forget to recharge when you are not using the equipment!

General instructions

The therapist will do the following: 1) touch the patient regularly; 2) advise the patient not to move during the relaxation period as the sensor is a movement sensitive device; 3) check to see whether the patient is contracting too many muscle groups at once, and/or not breathing during the contraction; 4) be careful not to overload the patient with too much information all at once; 5) encourage the patient to concentrate on the sensations in their muscles, especially when they are getting it right: " Did you feel that just now? How did it feel? Remember this sensation and try to recreate it during your next contraction"; 6) instruct the patient not to 'regrab' the muscles but rather to keep the contraction steady; 7) explain to the patient that trying harder does not always work: "If you're straining all over, you're not doing it right. Focus on the sensation; when it's right, you can always bring up the level of your contraction later on. It's better to have more control and less amplitude at first". The therapist can explain to the patient that "this is a neuromuscular activity, like riding a bike or playing tennis. It's not a forcefulness feeling, and you have to figure it out on your own. You can't explain how to ride a bike, but once you get it, you know it". The therapist can give the image of "sucking up the sensor"; 8) check manually to see if the super pubic tension is present; it should be there when the patient is contracting the right way. The patient can use muscle groups such as the inner thighs and the abdominals to aid in the contraction at first. They can be trained to use these accessory muscles at first and then gradually, as the strength of their contraction increases, they will be instructed to stop using them; 9) will give a lot of positive feedback to the patient and act as a coach.

In case of a cancellation, whether from the patient or the therapist, an appointment will be rescheduled as soon as possible, preferably during the same week as the initial

appointment. If the patient has their period, they can still come to their appointment. Just make sure the EMG signal is an authentic one (blood not interfering with it).

Session 1 (1 hour)

The therapist will have the name, patient number and file of the patient on hand. They will have reviewed the file in advance and Sophie Bergeron will have answered any questions they might have about the case.

THERAPIST

1. *Review*: Introduce yourself as Dr. X, clinical psychologist. " I will be your biofeedback therapist for the duration of the study. This is Dr. Howard Glazer from New York, the originator of biofeedback training for vulvar vestibulitis syndrome. We will first talk a bit about the history of your pain, and then Dr. Glazer will explain the treatment to you and will do the initial evaluation of your pelvic floor muscles. He will be here only for this first session as he wanted to meet every patient personally. Review history of patient: age, relationship status, when and how pain started, sexual activity. Make sure that you have their phone number. Encourage them to keep engaging in or to renew sexual activity (no sex therapy however). "The renewing of sexual activity has 2 purposes: a) you need to have orgasms to rehabilitate the muscles, as the muscle responsible for the sensation of orgasm is part of the group of muscles we will be working on during this therapy, and b) fear incubates: the less you have sex (due to fear of pain), the more your fear will grow, the more you will keep avoiding sex, and the less able you will be to resume a normal sex life once the pain is gone. Engaging in sexual activities that result in orgasm will thus facilitate the treatment. You need to start associating sex with pleasurable sensations again, whether via masturbation or other non-penetrative sexual activities. Do you have any questions? I'll now let Dr. Glazer explain the treatment to you".

2. *Rationale*: "I will explain the assessment procedure to you in a few minutes, but first let's talk about the rationale of the biofeedback training for vulvar vestibulitis syndrome (VVS). You may be wondering how working on your pelvic floor muscles will help alleviate pain in the tissue at the entry of your vagina. As you probably already know, we're not sure about the causes of VVS. Everybody has their own personal theory but none has been scientifically proven. The only sure thing we know is that many of the women suffering from your condition report a history of yeast infections. It's not clear yet how this is related to the pain. Gynecologists have started getting interested in this condition about 10-15 years ago. Many of them were noticing that women with VVS had tense pelvic floor muscles (I'll show these to you on a diagram in a couple of minutes). Since other treatments such as topical creams weren't very successful, they thought about looking more into how these tense muscles might be related to the pain. Doctors started sending patients to me, as I was already using biofeedback to treat urinary incontinence. Traditionally, biofeedback has been used to control the tension in muscles, either to relax them (as is the case with headaches) or the build strength (urinary incontinence). In the case of VVS, I am consistently finding that the muscles of women with this condition are unstable, tense and spastic at rest. Furthermore, women typically don't feel the muscle tension and have little control over these muscles. We think that this chronic tension and instability contributes to maintain the tissue pain by adding pressure to the nerves and blood vessels, thus creating a kind of vicious circle of pain. My previous studies show that when you break down the tension and get the muscle to relax, the pain disappears (show patient normal and abnormal graphs). Thus the goal of the biofeedback training is to gain more control over the pelvic floor muscles by doing regular exercises and to fatigue these muscles into relaxation. Your pain won't disappear all at once. You will probably notice times where you have no pain at all, and then at other times you will find your pain to be

just as bad or worse than it was before. In fact, you may find that during the first few weeks of biofeedback training, your pain will be somewhat worse than before. This is the normal healing process when undergoing this type of treatment. Do you have any questions at this point?"

3. *Procedure*: "What we're going to do today is to evaluate the resting tension level of your pelvic floor muscles, as well as the strength of your contractions. You can see here on the graph which muscles we are going to assess (show figure 8 in red). These are your pubococcygeal muscles, which we believe are maintaining your pain. I will ask you to privately insert a tampon-like device into your vagina in the washroom in the hall. You will insert it in the direction that puts the cord at the top, cord which will then simply hang from the top of your pants, since you will fully redress yourself after having inserted the sensor. You may experience some discomfort while inserting the device, but once it is inserted you shouldn't feel any pain. This is your personal sensor which you will bring home with you in order to do the home training exercises. You should always wash it with soap and water before and after using it. Here is some lubricant jelly to facilitate the insertion. You can use the same type of jelly at home (KY, Astroglide, etc.)". The patient will then go to the nearest washroom to insert the sensor.

4. *Assessment*: "How did it go? Are you feeling any pain? Come and lie down in the chair here". The therapist will place the recliner in a lying down position. "Are you comfortable? Place your heels together like this, with your legs outward". The therapist will place the patient's legs in the right position himself/herself. "This will help you to relax. Now I'm going to connect the sensor to the computer; you won't feel a thing". The therapist looks at the tension level at rest and chooses the proper screen (e.g. 25 Mv, 50 Mv, etc.). "If you look on the screen, you can see your pelvic floor muscles' resting tension level". The therapist can comment on what is on the screen in comparison to other profiles shown

earlier. The therapist will then ask the patient to contract their pelvic floor muscles and to hold the contraction for 10 seconds to make sure that she is able to voluntarily contract the correct isolated muscle group. In many cases the patient will have difficulty either in contracting the muscles, sensing the contraction or isolating the contraction to just the pelvic floor. They will practice these contractions with the therapist for about 5 minutes. The therapist can print out a graph to be kept in the patient's file which will be used to monitor progress, comparing it to graphs that will be produced later on. The therapist will then start the automated data collection protocol.

1. Three 20-second baseline periods.
2. Six 3-second contraction periods: the patient is asked to create one strong, brief contraction (sexual function of muscles). Each contraction is preceded by a 12-second rest period.
3. Twelve-second rest period.
4. Six 12-second contraction periods: the patient is asked to maintain her contraction and not to 'regrab' (sphincteric function of the muscles). Each contraction is preceded by a 12-second rest period.
5. Thirty to forty seconds of rest.
6. One 60-second contraction: the patient is asked to try to maintain the contraction above the yellow line (supportive function of the muscles).
7. Three 20-second post-baseline periods.

The therapist will then write in the data from the current session: patient name and #, intercourse or not in past 30 days (yes = 1, no = 2), pain rating of last pain, state of muscles, and homework. The data sheet will be printed and inserted in the patient's file.

5. *Home training*: The therapist will adjust the home trainer to the patient's level of contractions and will then instruct the patient on how to practice these exercises. "You will be practicing these exercises 20 minutes in the morning and 20 minutes at night (60 repetitions of the 10-second rest/10-second contract cycle). These need to be focused and intentional exercises. You have to concentrate on the sensations of your pelvic floor muscles and use the feedback of the home trainer to perfect your contractions and to see if you're relaxing the muscles. As the number of lights "on" go down during a contraction, try to strengthen the contraction. You should be exhausted by the end of the 20 minutes. If you're not, it's because you're probably not doing the exercises the right way. Do you have any questions?" The therapist will then provide the patient with written homework instructions.

THERAPIST

6. *Schedule*: "You will come here once a week for the following 3 weeks, and for the following 8 weeks you will come here every 2 weeks, for a total of 8 sessions over the course of a 12-week period, as explained in the consent form you signed. Each session will last about 45 minutes. Don't forget to do your regular exercises at home with the home trainer, as this is the most important part of the treatment. For this treatment to be effective, you need to be committed to it". The therapist should then confirm the following week's appointment and provide the patient with a phone number where they can be easily reached or where they can leave a message.

7. *Daily Pain Rating Forms* The therapist will give the envelope containing 3-months of forms (total duration of treatment). The therapist will instruct the patient to start filling out the forms the following Monday, for a duration of 2 weeks. She will then stop for the following 2 weeks, and then start again. The patient will receive more forms (for the 6-

month follow-up) when she goes for her post-treatment assessment at the Royal Victoria Hospital.

8. *Treatment expectancies* The therapist will ask the patient to fill out the Treatment Expectancies form. Once the form is filled out, the patient can leave.

9. *Compliance form* The therapist will fill out a Compliance form for every patient, after every session.

10. *Compliance brochure* The therapist will hand-out a compliance brochure to the patient and instruct her to refer to it for the remainder of the study.

Sessions 2, 3, 4, 5, 6, 7 (45 minutes to 1 hour)

1. *Review*: "How are you? How have your exercises been going? Are you encountering any problems? How is your pain? Do you have any questions about the home training?" Do a bit of small talk, discuss home training and pain. Fill out compliance sheet. Give them positive feedback. Encourage them to keep engaging in or to renew sexual activity (no sex therapy however). Repeat, if necessary, something along these lines: "The renewing of sexual activity has 2 purposes: a) you need to have orgasms to rehabilitate the muscles, as the muscle responsible for the sensation of orgasm is part of the group of muscles we will be working on during this therapy, and b) fear incubates: the less you have sex (due to fear of pain), the more your fear will grow, the more you will keep avoiding sex, and the less able you will be to resume a normal sex life once the pain is gone. Engaging in sexual activities that result in orgasm will thus facilitate the treatment. You need to start associating sex with pleasurable sensations again, whether via masturbation or other non-penetrative sexual activities".

2. *Procedure*: "Today we are basically going to do the same thing as last week, evaluating the resting tension level of your pelvic floor muscles, as well as the strength of your contractions. We're going to do a bit of practice, and then we will run the protocol". Tell the patient to go to the nearest washroom to insert the sensor.

3. *Assessment*: "Are you feeling any pain? Come and lie down in the chair here". The therapist will place the recliner in a lying down position. "Are you comfortable? Place your heels together like this, with your legs outward". The therapist will place the patient's legs in the right position himself/herself. "This will help you to relax. Now I'm going to connect the sensor to the computer; you won't feel a thing". The therapist looks at the tension level at rest and chooses the proper screen (e.g. 25 Mv, 50 Mv, etc.). "If you look on the screen, you can see your pelvic floor muscles' resting tension level". The therapist can comment on what is on the screen in comparison to how it was the week before and congratulate the patient on any progress that has occurred. The therapist will then ask the patient to contract their pelvic floor muscles and to hold the contraction for 10 seconds. Practice of these contractions with the therapist will continue for about 5 minutes, following the general instructions outlined at the beginning of the protocol. At the end of the practice session, the therapist can print out a graph to be kept in the patient's file, which will be used to monitor progress, comparing it to graphs that will be produced later on or that were produced in the past. The therapist will then start the automated data collection protocol.

1. Three 20-second baseline periods.
2. Six 3-second contraction periods: the patient is asked to create one strong, brief contraction (sexual function of muscles). Each contraction is preceded by a 12-second rest period.

3. Twelve-second rest period.

4. Six 12-second contraction periods: the patient is asked to maintain her contraction and not to 'regrab' (sphincteric function of the muscles). Each contraction is preceded by a 12-second rest period.

5. Thirty to forty seconds of rest.

6. One 60-second contraction: the patient is asked to try to maintain the contraction above the yellow line (supportive function of the muscles).

7. Three 20-second post-baseline periods.

The therapist will then write in the data from the current session: patient name and #, intercourse or not in past 30 days (yes = 1, no = 2), pain rating of last pain, state of muscles, and homework. The data sheet will be printed and inserted in the patient's file.

4. *Home training*: The therapist will adjust the home trainer to the patient's level of contractions and will then ensure that the patient is practicing these exercises correctly (not doing anything else at the same time, right position, etc.). The therapist can encourage the patient to take notes or to write down whatever questions they might have during the week. Repeat, if necessary: "You will be practicing these exercises 20 minutes in the morning and 20 minutes at night (60 repetitions of the 10-second rest/10-second contract cycle). These need to be focused and intentional exercises. You have to concentrate on the sensations of your pelvic floor muscles and use the feedback of the home trainer to perfect your contractions and to see if you're relaxing the muscles. As the number of lights "on" go down during a contraction, try to strengthen the contraction. You should be exhausted by the end of the 20 minutes. If you're not, it's because you're probably not doing the exercises the right way. "Don't neglect to do your exercises regularly with the home trainer, as this is the most important part of the treatment. For this treatment to be effective, you need to be committed to it. Do you have any questions?"

5. *Schedule*: The therapist should then confirm the following appointment.

6. *Compliance form* The therapist will fill out a Compliance form for every patient, after every session.

Session 8

1. *Review*: "How are you? How have your exercises been going? Are you encountering any problems? How is your pain? Do you have any questions about the home training?" Do a bit of small talk, discuss home training and pain. Fill out compliance sheet. Give them positive feedback. Encourage them to keep engaging in or to renew sexual activity (no sex therapy however). Repeat, if necessary, something along these lines: "The renewing of sexual activity has 2 purposes: a) you need to have orgasms to rehabilitate the muscles, as the muscle responsible for the sensation of orgasm is part of the group of muscles we will be working on during this therapy, and b) fear incubates: the less you have sex (due to fear of pain), the more your fear will grow, the more you will keep avoiding sex, and the less able you will be to resume a normal sex life once the pain is gone. Engaging in sexual activities that result in orgasm will thus facilitate the treatment. You need to start associating sex with pleasurable sensations again, whether via masturbation or other non-penetrative sexual activities".

2. *Procedure*: "We are again going to evaluate the resting tension level of your pelvic floor muscles, as well as the strength of your contractions. We're first going to do a bit of practice, and then we will run the protocol". Tell the patient to go to the nearest washroom to insert the sensor.

3. *Assessment*: "Are you feeling any pain? Come and lie down in the chair here". The therapist will place the recliner in a lying down position. "Are you comfortable? Place your heels together like this, with your legs outward". The therapist will place the patient's legs in the right position himself/herself. "This will help you to relax. Now I'm going to connect the sensor to the computer; you won't feel a thing". The therapist looks at the tension level at rest and chooses the proper screen (e.g. 25 Mv, 50 Mv, etc.). "If you look on the screen, you can see your pelvic floor muscles' resting tension level". The therapist can comment on what is on the screen in comparison to how it was the week before and congratulate the patient on any progress that has occurred. The therapist will then ask the patient to contract their pelvic floor muscles and to hold the contraction for 10 seconds. Practice of these contractions with the therapist will continue for about 5 minutes, following the general instructions outlined at the beginning of the protocol. At the end of the practice session, the therapist can print out a graph to be kept in the patient's file which will be used to monitor progress, comparing it to graphs that will be produced later on or that were produced in the past. The therapist will then start the automated data collection protocol.

1. Three 20-second baseline periods.
2. Six 3-second contraction periods: the patient is asked to create one strong, brief contraction (sexual function of muscles). Each contraction is preceded by a 12-second rest period.
3. Twelve-second rest period.
4. Six 12-second contraction periods: the patient is asked to maintain her contraction and not to 'regrab' (sphincteric function of the muscles). Each contraction is preceded by a 12-second rest period.
5. Thirty to forty seconds of rest.

6. One 60-second contraction: the patient is asked to try to maintain the contraction above the yellow line (supportive function of the muscles).
7. Three 20-second post-baseline periods.

The therapist will then write in the data from the current session: patient name and #, intercourse or not in past 30 days (yes = 1, no = 2), pain rating of last pain, state of muscles, and homework. The data sheet will be printed and inserted in the patient's file.

4. *Home training*: The therapist will adjust the home trainer to the patient's level of contractions and will then ensure that the patient is practicing these exercises correctly (not doing anything else at the same time, right position, etc.). "You will be practicing these exercises 20 minutes in the morning and 20 minutes at night (60 repetitions of the 10-second rest/10-second contract cycle) for the following 6 months, even though this is our last appointment. I will be calling you once a month for the following 6 months to discuss the exercises with you. When I call you, I will ask you to insert your sensor and to tell me what letter your resting tension level is at and what letter your contraction is at". Repeat, if necessary: "The contractions need to be focused and intentional exercises. You have to concentrate on the sensations of your pelvic floor muscles and use the feedback of the home trainer to perfect your contractions and to see if you're relaxing the muscles. As the number of lights "on" go down during a contraction, try to strengthen the contraction. You should be exhausted by the end of the 20 minutes. If you're not, it's because you're probably not doing the exercises the right way. "Don't neglect to do your exercises regularly with the home trainer, as this is the most important part of the treatment. For this treatment to be effective, you need to be committed to it. Do you have any questions?"

5. *Schedule*: The therapist should remind the patient of their follow-up assessment (end of June), and remind them as well not to tell Janet Bradley what treatment they have received. Wish the patient good luck.

6. *Compliance form* The therapist will fill out a Compliance form for every patient, after every session.

Appendix 19 - Participant Compliance Form

sEMG Biofeedback

Randomized Treatment Outcome Study

Patient compliance form

Biofeedback

Patient #: _____ Session #: _____

Date of appointment: _____

Name of therapist: _____

Was patient present? YES NO

How many home training practice sessions has the patient done in the last 7 days? (Min. = 0, Max. = 14). Write down the number of sessions.

_____

Additional comments:

_____

_____

_____

_____

Appendix 20 - Home Training Instructions for Participants

sEMG Biofeedback

Randomized Treatment Outcome Study

Home training instructions

How much time per day should I be doing these exercises?

20 minutes in the morning

20 minutes at night

Each 20-minute period is equivalent to 60 repetitions of the 10-second rest/10-second contract cycle.

How should I be doing the contractions?

1. Insert your personal sensor in your vagina, using some water-based lubricant if you want (e.g. KY, Astroglide, etc.). Plug the sensor into the home trainer. Place yourself in a comfortable position, in a room where you know you won't be disturbed. Do not do another activity at the same time (e.g. talking on the phone, watching TV, etc.). Your attention has to be entirely focused on your exercises. You can keep a clock or a watch nearby to make sure you're doing each set of exercises for a duration of 20 minutes.

2. You start your contraction when the light on your home trainer says "work", and you stop your contraction when the light says "rest".

3. During your home training, you will be doing the same kind of contractions that you learned to do with your therapist during your first biofeedback session. The contractions need to be focused and intentional exercises. You have to concentrate on the sensations of your pelvic floor muscles and use the feedback of the home trainer to perfect your contractions and to see if you're relaxing the muscles. As the number of lights "work" go down during a contraction, try to strengthen the contraction. You should be exhausted by the end of the 20 minutes.

What happens if I miss a 20-minute exercise period during a day?

If you happen to miss one of your morning practices, make up for it at some other time during the day (e.g. lunch time). If this is not possible, or if you miss an evening practice, just make sure you keep doing your two practices the next day and all of the following days. Another thing to do is to try to understand why you missed a practice session and to see what you could do to prevent this from happening again in the future. If one of the reasons is that you're feeling discouraged, or that you're not sure if you're doing your exercises properly, discuss it with your therapist. She is there to help you.

How long will it be before I start seeing an improvement in my pain?

During the first few weeks, you may actually experience an increase in pain intensity. This is a normal part of the treatment process. After those first weeks, you will start experiencing diminished pain intensity, although this will not happen all at once. Sometimes, you will feel almost no pain, and other times, you will feel as though your pain has increased again. These kinds of variations in pain intensity are to be expected. Patience and practice are your best allies!

Instructions pour les exercices à la maison

Combien de temps par jour dois-je consacrer à ces exercices?

20 minutes le matin
20 minutes le soir

Chaque période de 20 minutes équivaut à 60 répétitions du cycle de 10-secondes-repos/10-secondes- contraction.

Comment dois-je faire les contractions?

1. Insérez votre sonde personnelle dans votre vagin, en utilisant un lubrifiant à base d'eau si vous le désirez (ex.: KY, Astroglide, etc.). Branchez la sonde dans votre appareil de biofeedback portatif. Installez-vous dans une position comfortable, dans une pièce où vous ne serez pas dérangée. Vous ne devez pas faire une autre activité en même temps (ex.: parler au téléphone, regarder la télévision, etc.). Votre attention doit être entièrement focalisée sur vos exercices. Vous pouvez garder une horloge ou une montre près de vous afin de vous assurer que vous faites chaque séance d'exercices pour une durée de 20 minutes.

2. Vous commencez votre contraction quand la lumière sur votre appareil portatif indique "work", et vous arrêtez votre contraction quand la lumière indique "rest".

3. Durant vos pratiques quotidiennes, vous allez exécuter le même genre de contractions que vous avez appris à faire avec votre thérapeute lors de votre première séance de biofeedback. Les contractions doivent être exécutées avec intention et concentration. Vous devez vous concentrer sur les sensations dans vos muscles pelviens et utiliser le "feedback" de votre appareil portatif afin de perfectionner vos contractions, ainsi qu'afin de voir si vous détendez bien vos muscles. A mesure que le nombre de lumières "work" diminuent durant une contraction, essayez de renforcer cette contraction. Vous devriez être épuisée à la fin du 20 minutes.

Qu'arrive-t-il si je manque une de mes séances d'exercice durant une journée?

Si vous manquez une de vos séances du matin, reprenez-la à un autre moment de la journée (ex.: au dîner). Si cela n'est pas possible, ou si vous manquez une de vos séances du soir, assurez-vous seulement de continuer à pratiquer vos exercices deux fois par jour le lendemain et tous les jours qui suivront. Une autre chose à faire est d'essayer de comprendre pourquoi vous avez manqué une séance de pratique et de penser à ce que vous pourriez faire afin de vous assurer que cela ne se reproduise plus. Si une des raisons est que vous vous sentez découragée, ou que vous n'êtes pas certaine de bien faire les exercices, discutez-en avec votre thérapeute. Elle est là pour vous aider.

Combien de temps cela prendra-t-il avant que je commence à voir une amélioration de ma douleur?

Durant les premières semaines, vous allez probablement ressentir une hausse d'intensité de la douleur. Ceci est une composante normale du processus de traitement. Après ces premières semaines, vous commencerez à ressentir une diminution de l'intensité de la douleur, quoique ceci ne se produira pas d'un seul coup. Parfois, vous ne ressentirez presque pas de douleur, et d'autres fois, vous aurez l'impression que votre douleur est plus forte. Vous pouvez vous attendre à de telles variations dans l'intensité de votre douleur. La patience et la pratique sont vos meilleurs alliés!