TOWARDS EVIDENCE BASED PRACTICE IN PELVIC FLOOR PHYSIOTHERAPY

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Towards evidence based practice in pelvic floor physiotherapy

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Aan John, Martijn en Jeroen
Aan mijn vader † en moeder
Aan Hans Delemarre †

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Chapter 1

General Introduction and Outline

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From the Department of Urology of the Leiden University Medical Center

The Netherlands

History of the physiotherapy

For all we know, physiotherapy has always played an essential role in the process of rehabilitation. Since thousands of years people with illnesses and disorders were treated with various methods, making use of exercises and massage as well as water, heat and cold, electricity and light. The ground for the introduction of medical gymnastics in the Netherlands was prepared around 1840 (1) .

When we state that the origins of Dutch Physiotherapy have to be looked for in the first half of the nineteenth century we have to be aware of the fact that the use of the word physiotherapy is of course inappropriate here. It is an anachronism, for it was no sooner than the end of the nineteenth and beginning of the twentieth century that words like *Physikalische Heilmethode, Physikalische Therapie, Physical Therapy and Physiotherapy* were used as a generic term that stood for a complex of different therapies, which included exercises, massage, hydrotherapy, balneo therapy, electrotherapy, light and air-therapy, cryo- and heat-therapy (2).

The first signs of the actual use of these therapies were spotted in publications around 1840.

The spreading of the Enlightenment-ideas on education-mainly coming from Germany had already been of influence on the way of thinking about the educational system in the Netherlands in the years before 1848. It was emphasized in various Dutch publications on education that mental education was heavily overrated in the schools and more attention should be paid to physical education (3).

With the ongoing discourse on the importance of physical education within the educational system, teachers and physicians gradually became more receptive for other views on how to use gymnastic exercises. In their classrooms and practices they often were the first to be confronted with children who suffered from disablements and illnesses. Since conventional medical interventions had barely or no effect, the enthusiastic reports from Sweden and Germany must have led these teachers and physicians to believe that what was called “medical gymnastics” could be a remedy to cure these kinds of disorders.

In the second half of the 19th century the interest for the application of medical gymnastics increased. It was considered a ‘relative new and very promising field in medicine’ by some physicians and was more and more referred to as ‘heilgymnastics’ (heilgymnastiek).

In July of the year 1889 two heilgymnasts, E.Minkman (1848-1912) and J.H.Reijs Jr. (1854-1913) send a circular to nine of their colleagues with an invitation for a meeting. They wrote that heilgymnasts should unite themselves in solving the problems that the field of heilgymnasts was facing. The many different ways to treat patients with certain disorders asked for a thorough analysis to separate the good treatments from the bad. This resulted in the founding of the Society for Practicing Heilgymnastiek in the Netherlands (Genootschap ter beoefening van de Heilgymnastiek in Nederland, hereafter referred to as Genootschap). Physicians began to take an interest in heilgymnastics and other forms of physical therapy on a bigger scale. In an attempt to gain control over this particular field of medicine, three similar organizations were founded in this period by physicians, who were active in the field of physiotherapy and orthopedics (in both of these fields heilgymnastics was included): the Dutch Orthopedic Association (Nederlandse Orthopaedische Vereeniging) in 1898, the Medical Association for Physical Therapy and Hygiene (Geneeskundige Vereeniging voor Physische Therapie en Hygiëne) in 1902 and the Association for Physical therapy (Vereeniging voor Physische Therapie) in 1903. The members of the Genootschap tried to acquire the legal status for their profession in many different ways, but it would last until 1942, fifty years after the foundation of the Genootschap before heilgymnastics received the legal status. During the German occupation, an act was sanctioned that stated that heilgymnastics was to be regarded as a “paramedical” in stead of a “medical” activity. At the moment research on the developments in the field of physiotherapy in The Netherlands in the late nineteenth and first half of the twentieth century is in progress, by Dr. Thom Terlouw, secretary of the association of the History of the Physiotherapy in the Netherlands.

Physiotherapy is a term which was coined by the Office of the Surgeon General of the Army to describe what until then had been known amongst the profession as “physical therapeutics” , and which is now also called “physical therapy” (4). Many believe that to have an understanding of physical therapy requires a deep study of electricity and physics. According to Titus this is not necessary because it is easy to recall what we all studied in physics and physiological laboratories. Since it is not necessary that one knows exactly how to administer treatments in order to prescribe them, it does not require very deep painstaking study to acquire knowledge of the fundamentals.

The biggest part of physical therapy is medical common sense. An understanding of the pathology and of what reaction you desire to bring about in the patient can be

called the common sense part. Three percent of physical therapy is technical knowledge of whether the modalities can be applied effectively, conveniently and safely to the part to be treated and how those modalities will work when brought into play. Two percent of physical therapy is the actual knowledge of the technique so that you yourself can administer the treatments. Therefore, the common sense part of the subject is ninety-five per cent. The basic action of practically all physical therapy is chemical, thermal or mechanical (4).

In the beginning of the 1980's application forms disappeared from the package of insurance. Most physiotherapists decided not applying some treatment methods anymore, e.g. electrostimulation. Within the pelvic floor physiotherapy electrostimulation remained standard care. It is remarkable electrostimulation is nowadays also standard care in cardiology (5), neurology (6) and urology (7).

History of the pelvic floor disorders

The pelvis and its pelvic floor have always interested scientists. In modern times, the study of the genital apparatus of male and female is highly advanced. Despite this, knowledge of the muscles, nerves and ligaments of the pelvis and its organs has allowed priority in current research. Urinary and fecal incontinence, a most serious problem for young and elderly people is, due to lack of knowledge of the normal structure and function of the pelvis, a poorly understood affliction. Moreover the layman is badly informed, and incontinence is still regarded as shameful, which also hinders research (8). The birth of the scientific Anatomy in Europe can easily be pin-pointed. Andreas Vesalius (1514-1564) is the scientist who changed the title of the anatomical science in favor of a real analysis of the human body (9;10). In his opus magnum "*de humani corporis Fabrica libri septum"* , Vesalius gave only a superficial description of the internal musculature of the pelvis, but he paid much attention to the male genital apparatus in the part *"de musculis penis peculiaibus"*. He did show the bony pelvis to consist of three bones: os ilium, os coxendicum and os pubis, that were present on both sides of the os sacrum. Attention was given to the ossi cocygyx as being vertebrae containing holes for the nerves. This description corresponds to the modern view in the relationship with sacral neuro modulation (SNS).

Hendrik van Deventer (1651-1724) studied the form and the width of the bony pelvis in female, and is considered founder of the "pelvic science" (11). Van Deventer was

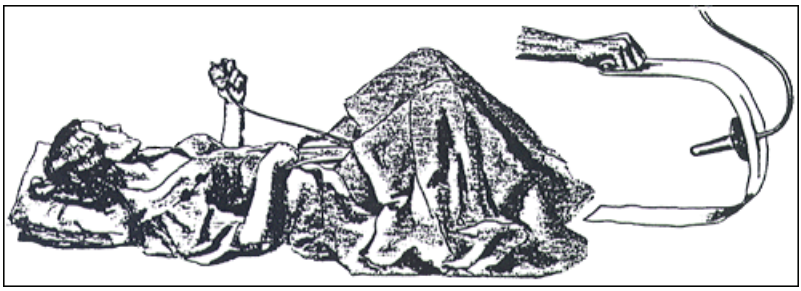
deeply interested in obstetrics. In those days, the entry of a physician into the delivery room, in which a man should not be present during delivery, indicated that something was badly wrong. He teached the midwives about the pelvis, its bony structure and their different appearances, because he thought the knowledge of the bones to be genuinely necessary for all those who want to help women in delivery. The idea of the narrowed pelvis as the cause of a difficult delivery had already been pointed out by Vesalius. The pelvic bones should part to make way for the child.

History of urology

The knowledge of the changes which urine, this very important excretory product of our body, was already recognized in antiquity and examined with utmost shrewdness with respect to health and disease. An attempt was made to identify the relation between the patient's condition and his urine. The written history of uroscopy starts 4000 years ago with scripts of Babylonian medicine. In ancient Greece, Hippocrates (469-399 B.C.) repeatedly described the usefulness of uroscopy in diagnosis and prognosis. He pointed out of the influence of food and drink on secretion, color, odor and translucency of the urine (12). Paulus Aegineta (± 660) also explained the importance of uroscopy for the diagnosis and he described clearly the possibility of solving the problem of bladder stones (13) by different types of bladder irrigation. For all practical purposes, the world shrunk considerably in size as we enter the beginning of the Dark Ages. Medical education became only available at the various monasteries who kept the manuscripts of the early writers. Surgical education was at that time the same as for all craftsmen and consisted of closely observing the experienced and spending a lot of time as a helping hand at the surgery and in the barber-shop. The middle ages are not known for their great achievements in the field of medicine and/or surgery.

History progressed in the Netherlands at a slow pace. In the archives evidence is found that traveling lithotomists were active in several places. The barber-surgeons practiced bleeding, cupping and minor surgery. During the middle ages, all accounts of lithotomy describe very much the same technique. In the fourteenth century, barber-surgeons became organized into guilds, the guild of Surgeons and Barbers combined their interests. So, during the eighteenth century, surgery became respectable. Lithotomy was at last accepted and began to take its place as one of the

most important operation of surgery. A promising step was the foundation of the Dutch society of Medicine in 1849 and in 1902, the Dutch society for surgery was founded in Amsterdam. The urologists in Holland derive from this group of early specialists. Only with the rapid development of endoscopic instruments and the refined diagnostic use of the X-ray, the urological specialization was finally accepted.
The Dutch Association “de Nederlandse Vereniging voor Urologie” was founded in 1908. The further development of sophisticated instruments and the refinement of the diagnostic possibilities created a situation in which the general surgeons had to make way for urologists. Until after the Second World War, most doctors had to go abroad for an up-to-date training in urology. It was not until January the 1th 1965 dr. W.A. Moonen had been appointed as an extraordinary professor in Nijmegen in order to organize an academical department of Urology. On April 1th 1962 dr. P.J. Donker became an extraordinary lecturer of Urology in Leiden. On January 1th 1965 he became an extraordinary professor of Urology in Leiden shortly after the appointment of dr. W.A. Moonen and 1968 the first full professor of Urology in the Netherlands.
Urology has now become a fully fledged specialism and research started. Within the urology, different specialisms developed in time, such as the oncology and the functional urology, the area where Urology and pelvic floor physiotherapy met each other, followed by gynecology and proctology resulting in the first Pelvic Floor Center in Leiden (1996).



Dr. Kegel's perineometer

History of pelvic floor physiotherapy abroad

In 1948 Arnold Kegel, MD (14) stated that, "the passage of the fetal head through the vagina during delivery is inevitably attended by muscle injury. Never, however do the organs resume their original integrity of form and function." While noting the equal occurrence of pelvic floor muscle weakness in women who did not gave birth to children, in 1956 he stated that, "the stretching process of childbirth... is merely a precipitating factor and not the primary cause of pelvic floor muscle weakness", but the lack of exercise and consequent muscle atrophy is. Optimistically, he noted that, "after having been stretched over a wider range than any other muscle (the pelvic floor muscles) can regain physiological tension and are able to recover their function after many years of disuse and partial atrophy". He proclaimed, "... it is not enough merely to keep a woman alive; it is important to preserve function... ,the relaxation of the vaginal outlet (and muscle responsible for urinary control, pelvic organ support, and sexual response) is caused by a lack of tone of the (pelvic floor) muscles".

Prior to World War II the accepted treatment of injured or weakened muscles was prolonged rest and passive exercise. According to a War summary, when treating disabled veterans, it was found that, "in the preservation or restoration of muscle function nothing is more fundamental than the frequent repetition of correctly guided exercises... carried out against progressively increasing resistance, since muscles increase in strength in direct proportion to the demands placed on them".

Dr. Kegel further observed that in a large series of women, the same percentage of women who had not gave birth to children compared to those who had, suffered symptoms of pelvic discomfort, bladder dysfunction and sexual disturbances. He concluded that for all women, "early pelvic floor muscle education and resistive exercise offer new hope in lasting relief ".

The need for a method in which the pelvic floor muscles may be preserved and developed has long been recognized. Hippocrates tried oil clysmata, hot showers and ointments; Soranus (110 A.D.) attempted support by hand. Kegel tried the cumbersome, awkward curved spatula retained perineometer in 1948.

Today, most people refer to the vaginal squeeze, hold, and release exercises as Kegel's exercise. Dr. Kegel's perineometer (pictured above) which gave resistance to this exercise and made it work has long been forgotten.

History of pelvic floor physiotherapy in the Netherlands

The Dutch Association for Physical Therapy for Pelvic Floor Disorders and Pre- and Postnatal Healthcare (NVFB) originated from the NVFP, the Dutch association for physiotherapy and pre- and post-partum health care. The NVFP was founded in 1981. The association's main activities dealt with physiotherapy in regard to pregnancy and birth.

At the end of the eighties pelvic floor problems started to generate a lot of attention. These problems were firstly noticed in the peripartum care. At that time it appeared to be logical that this "new" patient population consulted the physiotherapists practicing the Pre- and Postnatal Healthcare.

The treatment of pelvic floor-dysfunction has taken off in the years that followed and soon not only women but also men and children were seen for treatment. Although pelvic floor dysfunction has long been related to the lower urinary tract and, more recently, to lower gastrointestinal symptoms, it is now considered to be an influential factor in the normal function and behavior of the genital system in both men and women. Invasive procedures whilst treating these disorders also evolved, e.g. research when treating pelvic floor dysfunction using invasive palpation and/or massage, myo-feedback, electro-stimulation and the rectal practice-balloon. Safeguarding the quality of treatment is one of the main occupations of the NVFB.

The interwovenness of complaints in the areas of the abdomen, the pelvic floor and the lower back has become increasingly evident over the past years. This has resulted in a description of the functions and competences of the pelvic floor physiotherapist. Thus, official standards and requirements for the educational program for pelvic floor physiotherapists were created by the NVFB. Physiotherapists must hold an official certification in order to be able to enroll in the special register for pelvic floor physiotherapists.

At the end of 2003 pelvic floor therapy received official recognition as a specialization within general physiotherapy in the Netherlands.

Literature is scarce on the topic of pelvic floor investigation. Quantification of the function of the pelvic floor muscles is not easy, due to the lack of simple to use and reliable measurement techniques and the lack of cut-off values for pathological conditions. Furthermore the reproducibility of testing is questionable. Research on this topic is important, because many people suffer from the consequences of pelvic

floor dysfunction. Pelvic floor dysfunction affects social, psychological, domestic, occupational, physical and sexual life.

Aims and outline of this thesis

This thesis discusses the basic science and applications of pelvic floor dysfunction. First of all during the diagnostic process a complete medical and injury history should be documented. Our department has developed a new administered questionnaire in Dutch: the Pelvic Floor Inventories Leiden (PelFIs) for men and women, in an attempt to create a new condition-specific pelvic floor questionnaire addressing all symptoms of micturition, defecation and sexual dysfunction related to pelvic floor dysfunction for use by professionals active in this field (Chapter2).

During the validation of the PelFIs in the total population with and without pelvic floor complaints a high percentage (13, 3%) of sexual abuse was reported.

A selection of patients has been evaluated in our Pelvic Floor Center. This outpatient Pelvic Floor Center is a specialized part of our Urological department and consist a surgeon, gynecologist, urologist and a pelvic floor physiotherapist. Routinely all new patients were sent in advance a voiding diary and a questionnaire on pelvic floor complaints to be completed at home and discussed at the first visit of our Pelvic Floor Center. This questionnaire contains questions on defecation, lower urinary tract symptoms, obstetric information and also sexual complaints. One of the questions is about sexual abuse.

We were interested how reliable this standard self-administered questionnaire is in detecting the number of patients admitting sexual abuse (Chapter 3).

Before beginning therapy, specialists use various diagnostic tools such as urodynamics, a voiding diary, defecogram or even MRI. However, current diagnostic models have stressed the importance of a physical exam, as well as assessment of the relationship between pelvic floor function, sexual function, isolated functioning and the awareness of the relationship between structures like the bladder, rectum, anus and vagina. The aim of this study was, in this perspective, before starting treatment, to perform a specific diagnostic work-up focused on pelvic floor function. In our hospital, this diagnostic consultation is indicated as DIPFF: Diagnostic Investigation of Pelvic Floor Function (Chapter 4).

Intravaginal, intra-anal electrostimulation and biofeedback training are used for treatment of urinary urge- and stressincontinence, anal dysfunction, and sexual dysfunction. For optimal treatment, knowledge of the structures that are the main targets in stimulating and in biofeedback training is needed. This knowledge of both the anatomy of the pelvic floor and physiological aspects should result in optimal design of probes. However, lack of uniformity in description of the anatomy per se, the nomenclature of the pelvic floor, and stimulation techniques has been hampering such a design. Moreover, the available, commonly used probes have been developed empirically (Chapter 5).

Electrical stimulation of the pelvic floor was reported to be an effective alternative treatment. Extracorporeal magnetic innervation therapy (ExMI) is a more recent technique. In the present pilot study we evaluated the effects of ExMI, to assess whether ExMI is suitable for our patients (Chapter 6).

In literature the effect of neurostimulation at the level of the Tibial nerve [(invasive: Posterior Tibial Nerve Stimulation (PTNS)] and direct stimulation on the dorsal sacrum [neuromodulation or Transcutaneous Electrical Nerve Stimulation (TENS) S2-S3] have been described. The effect of the procedure has been attributed to stimulation of the afferents to the bladder. Both procedures have been used at our institution with varying success. Some patients appeared to be refractory to either procedure. In order to increase the success rate we have tried if the combination of both procedures would increase yield of the stimulation.

We decided to combine TENS on the tibial nerve and TENS applied at the S2-S4 foramina. We performed this study to quantify the acute effect of one single application of TENS in patients with symptoms of the overactive bladder syndrome using urodynamic parameters (Chapter 7).

The lack of controlled parameters has made it difficult to evaluate the true efficacy of intravaginal electro stimulation (ES). Moreover the stimulation equipments as well as the treatment regimens are not standardized and it is difficult to draw conclusions about electrical parameters of frequency, pulse duration, pulse – to - rest ratio, length of treatment, power and accurate success rates. Based on previous studies, induction of bladder inhibition is most effective when using a frequency of 5-10 Hz.

We performed this study to quantify the acute effect of one single application of intra-vaginal ES in patients with symptoms of the overactive bladder syndrome using urodynamic parameters (Chapter 8).

In Chapter 9 the summary and conclusions of this thesis are presented. The Dutch translation can be found in Chapter 10.

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Chapter 2

Development and Validation of the Pelvic Floor Inventories Leiden (PelFIs)

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Introduction

The pelvic floor controls individual and integrated functions, sustains proper anatomic relationships between pelvic visceral organs and their outlets, and shares the basic mechanism with various visceral organs which function it controls. The pelvic floor is the binding element between these organs. Lower urinary tract, lower gastrointestinal and sexual dysfunctions are due to pelvic floor dysfunction (1). Literature is scarce on the topic of pelvic floor investigation and treatment.

Assessment of the function of the pelvic floor muscles, as in muscle strength, tone, endurance and coordination, is not easy, due to a lack of simple to use and reliable measurement techniques, and a lack of cut-off values for pathological conditions. Furthermore, the reproducibility of testing is questionable.

Research on this topic is important, because many people suffer from the consequences of pelvic floor dysfunction such as loss of urinary control. Pelvic floor dysfunction affects the social, psychological, domestic, occupational, physical and sexual lives of 15% to 30% of women of all ages (2). Despite the fact that urinary incontinence can lead to a social handicap, only 28% of women and men seek help for their symptoms. The main reason for not seeking help is the fact that the complaints are not considered to be serious enough by the patients and many health professionals (3).

During the diagnostic process a complete medical and injury history should be documented (4, 5). A number of standardized questionnaires are available, for example the Pelvic Floor Distress Inventory (PFDI), the Pelvic Floor Impact Questionnaire (PFIQ) (6), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) (7) and the King's Health Questionnaire (KHQ) (8, 9). These questionnaires assess parts of pelvic floor dysfunction and/or quality of life, have been developed for specialists in Urology and Gynaecology and are not focused on pelvic floor dysfunction in a broad sense related to micturition, defecation and/or sexual dysfunction. Only the recently published Electronic Pelvic Floor Assessment Questionnaire (e-PAQ) assesses all aspects of pelvic floor dysfunction (10).

Our department has developed a new administered questionnaire, the Pelvic Floor Inventories Leiden (PelFIs) for men and women in Dutch, in an attempt to create a new condition-specific pelvic floor questionnaire addressing all symptoms of micturition, defecation and sexual dysfunction related to pelvic floor dysfunction for

use by professionals active in this field. The PelFIs questionnaire has also been developed in an attempt to create more uniformity in history taking in patients with symptoms of pelvic floor dysfunction and thus increasing quality of care.

Methods

Questionnaire

The inventory items were identified from a comprehensive literature review, and form 9 different domains: 1.symptoms of prolapse (1 in men, 4 in women), 2. micturition pattern (13 in both men and women), 3. urinary incontinence (14 idem), 4. obstructive micturition (6 idem), 5. defaecation pattern (6 idem), 6. faecal incontinence (18 idem), 7. constipation (5 idem), 8. pelvic floor pain (6 in men, 5 in women), 9. sexual functioning (8 in men, 12 in women). The end version resulted in the PelFIs, an 83 – item instrument in women and a 76- item instrument in men, instrument measuring the degree of pelvic floor dysfunction. A validated scale (5 items) was added regarding erectile dysfunction (the IEEF, short form) (11, 12) to ensure that the full range of issues relating to symptoms of pelvic floor dysfunction was addressed. The main body of the questionnaire is identical for both men and women except for prolapse and sexual dysfunction.

Questions were grouped that, from a clinical point of view, should configure a domain.

Participants

The PelFIs was administered to healthy volunteers (N = 120) who did not search for help and did not use medication regarding symptoms of micturition, defecation and sexual dysfunction related to pelvic floor dysfunction. The volunteers were approached through various means; they were informed about the research and asked for their cooperation. Consenting men and women were approached by telephone to make an appointment. The PelFIs was also administered to men and women with symptoms of micturition, defecation and sexual dysfunction related to pelvic floor dysfunction (N = 100) randomly selected from the database of the Pelvic Floor Center at the Leiden University Medical Center (LUMC). A random sample of 30 patients was interviewed twice at a two-weekly interval to assess test-retest reliability. The interviewers were trained in our center to administer the questionnaire.

Table 1. Cronbach's Alpha and mean score (± SD) by domain of the Female PelFIs questionnaire

Domain total *(no of items)*	**Total**	**Volunteers**	***(n=87)***	**Patients**	***(n=60)***	**P**
	Cronbach's Alpha	*Mean*	*Std. deviation*	*Mean*	*Std.deviation*	
Prolaps (4)	0.65	2.44	5.83	31.94	6.54	0.0001
Micturition pattern (13)	0.77	23.75	9.36	45.05	16.49	0.0001
Urinary incontinence (14)	0.85	19.28	18.32	29.22	26.46	0.022
Obstructive micturition (6)	0.69	11.86	11.48	37.88	21.00	0.0001
Defecation pattern (6)	0.60	4.20	6.46	11.26	12.51	0.0001
Faecal incontinence (18)	0.68	6.54	7.29	16.23	15.05	0.0001
Constipation (5)	0.72	23.87	16.20	35.35	25.84	0.0001
Pelvic Floor pain (4)	0.69	7.90	9.88	22.18	24.14	0.001
Sexual function (2)	0.51	NA	NA	NA	NA	NA

**Questions must be added in the womens domain sexual function*

Statistical analysis

Data analyzed using SPSS for windows (release 14.0). Summary scale-scores were calculated by summing the item scores (without weighting), and transforming these to a 0-100 score. A higher score indicates more symptoms.

Reliability

Two types of reliability of the PelFIs questionnaire were assessed: internal consistency and test-retest reliability. Internal consistency was measured using Cronbach's Alpha statistics (12, 13). It has been suggested that an Alpha value of $\geq$ 0.7 is acceptable for group level purposes (research) (14). Items were either retained or deleted based on Cronbach's α and an item total correlation deleted of (< 0.20). In some instances however, items were retained despite reductions in α or low item total correlation for clinimetric reasons.

Test-retest reliability provides a measure of instruments stability over time (15). Test-retest reliability for the scales was assessed by intraclass correlation coefficients.

Validity

Construct validity was assessed by intercorrelating all domains, using Pearson's correlation coefficient. A $p< 0.01$ level was considered to indicate statistical significance. From a clinical point of view we hypothesized that in women's questionnaire the domains micturition pattern should correlate with the domains obstructive micturition, faecal incontinence and pelvic floor pain. The domain urinary incontinence should correlate with the domain faecal incontinence, the domain obstructive micturition should correlate with the domains faecal incontinence, constipation and pelvic floor pain, the domain constipation should correlate with the domains faecal incontinence, defecation pattern and pelvic floor pain.

In the men's questionnaire we hypothesized that the domain micturation pattern should correlate with obstructive micturition, constipation and erectile dysfunction. The domain urinary incontinence should correlate with obstructive micturition and faecal incontinence. The domain defecation progress should correlate with faecal incontinence, constipation and pelvic floor pain. The domain faecal incontinence should correlate with constipation and pelvic floor pain.

Tabel 2: Cronbach's Alpha and mean score (± SD) by domain of the Male PelFIs questionnaire.

Domain total *(no of items)*	**Total**	**Volunteers**	***(n=33)***	**Patients**	***(n=40)***	**P**
	Cronbach's Alpha	*Mean*	*Std. deviation*	*Mean*	*Std.deviation*	
Prolaps*(1)	NA	NA	NA	NA	NA	N/A
Micturition pattern(13)	0.76	20.59	5.64	42.58	18.90	0.0001
Urinary incontinence(14)	0.82	3.67	7.58	21.03	24.28	0.0001
Obstructive micturition(6)	0.68	7.13	7.31	33.16	21.72	0.0001
Defecation pattern(6)	0.47	9.78	7.74	16.77	12.13	0.008
Faecal incontinence(18)	0.69	5.66	5.50	18.66	19.22	0.0001
Constipation (5)	0.53	21.67	14.01	41.20	18.55	0.0001
Pelvic Floor pain(4)	0.83	14.02	12.41	35.34	30.56	0.0001
Erectile dysfunction(5)	0.90	32.27	11.10	49.06	29.40	0.022

**Prolapse (rectal) is a one-item domain and is thus excluded from this table.*

We also hypothesized that the domain urinary incontinence should correlate with the number of pads used. Known groups' validity was assessed by comparing scores of healthy subjects and patients. Differences between healthy volunteers and patients were assessed by means of T-tests.

Results

One hundred and thirty volunteers were invited to participate. Of these, ten volunteers decided not to cooperate afterwards.

A total of 220 men and women completed the PelFIs. 147 Women completed the questionnaire, of which 60 were patients with known Pelvic Floor Dysfunction (PFD) (mean age 43 years; range 12-76), and 87 were controls (mean age 45; range 21-79). Of the 73 men who took part in the study, 33 (mean age 50 years; range: 23-72) had known PFD and 40 (mean age 51; range 24-81) were controls. Time to complete the PelFIs ranged from 18 to 32 minutes.

Reliability

The internal consistency of the 9 domains was assessed using Cronbach's alpha (Table 1, 2). In the women's questionnaire only the domain sexual function had a low alpha of 0.51.

In the men's questionnaire, defecation progress had an alpha value of 0.47 and constipation had an alpha of 0.53.

Despite the low alpha of some domains, from a clinical point of view, items were retained.

Domain micturition pattern in men: "Do you notice more urgency, "What is the flow normally like"? The questions have a low item total correlation, but from a clinical point of view this question can not be removed because it contains information about an involuntary relaxation during micturition. Cronbach's alpha with this question is 0.76, without 0.77 in the men's questionnaire.

The domain defecation pattern in men. Without the question "Have you ever had an itch around the anus" the α would be 0.51, with the question α 0.47. Itching gives us much information about soiling. Without the question "Can you hold in wind via the anus" the α would be 0.60.

The domain faecal incontinence. Including the question "Can you put off the urge to

empty your bowel for 15 minutes?" this scale has an alpha of 0.69 in men and 0.68 in women. Without this question the alpha of this domain is 0.75 in men, but again from a clinical point of view this question should not be removed.

The domain pelvic floor pain. "Did you ever have cramp around the anus at night?"; "Do you ever have abdominal pain during a bowel movement". Cronbach's alpha with these questions is 0.69 in women and 0.68 in men, without these questions the alpha is 0.81 in women and 0.83 in men.

The domain prolapse in men contained not enough questions to form a domain.

Test-retest reliability, assessed with an Intraclass Correlation Coefficient (ICC) was 0.90 for the total PelFIs and over 0.70 for all domains but constipation (0.65) and pelvic floor pain (0.67).

Table 3. *Test-retest reliability (n=30)*

Domains	Intraclass correlation
Micturition pattern	0.82
Urinary incontinence	0.75
Obstructive micturition	0.88
Defecation pattern	0.77
Faecal incontinence	0.83
Constipation	0.65
Pelvic floor pain	0.67
Erectile dysfunction	0.88

Validity

Differences between healthy volunteers and patients were large and statistically significant for all domains. The smallest difference was seen for erectile dysfunction ($p=0.02$) in men and urinary incontinence in women ($p=0.02$).

Correlations of the domain scores were as hypothesized (Table 3, 4). The domain urinary incontinence correlated highly with the use of pads ($r =0.73$, $p< 0.001$).

Table 4.Correlations domains womens questionnaire

Pearson Correlation	Prolaps	Micturation progress	Urinary incontinence	Obstructive micturition	Defaecation Progress	Faecal incontinence	Constipation	Pelvic floor pain	Sexual function
Prolaps	1								
Micturition pattern	.143	1							
Urinary incontinence	.271(**)	.348(**)	1						
Obstructive micturition	.063	.669(**)	291(**)	1					
Defaecation pattern	.032	.445(**)	.053	.297(**)	1				
Faecal incontinence	.049	.424(**)	.397(**)	.335(**)	.483(**)	1			
Constipation	.089	.330(**)	.131	.419(**)	,427(**)	.290(**)	1		
Pelvic Floor pain	-.054	.326(**)	.122	.421(**)	.381(**)	.282(**)	.507(**)	1	
Sexual function	.321(**)	.351(**)	.347(**)	.412(**)	.381(**)	.365(**)	.482(**)	.667(**)	1

** Correlation is significant at the 0.01 level (2-tailed).

Table 5. Correlations domains mens questionnaire

Pearson Correlation	Micturation Progress	Urinary incontinence	Obstructive micturition	Defaecation Progress	Faecal incontinence	Obstipation	Pelvic floor pain	Erectile Dysfunction
Micturition pattern	1							
Urinary incontinence	.367(**)	1						
Obstructive micturition	.797(**)	.353(**)	1					
Daefecation pattern	.171	-.006	.152	1				
Faecal incontinence	.238(*)	391(**)	.211	.421(**)	1			
Constipation	.382(**)	.225	.371(**)	.535(**)	.474(**)	1		
Pelvic floor pain	.224	-.054	.313(**)	.632(**)	.359(**)	.505(**)	1	
Erectile Dysfunction	.376(*)	.339(**)	.527(**)	-.130	-.162	-.024	.017	1

** Correlation is significant at the 0.01 level (2-tailed).

DISCUSSION

Van der Vaart et al stated that 57% of the Dutch women age 45-70 appear to have complaints of urinary incontinence (16). In our opinion this amount may be even higher, because in our study 50% of the healthy volunteers had some complaints of urinary incontinence without seeking for medical advice. The term “pelvic floor dysfunction” has different meanings for different clinicians. From our point of view, the pelvic floor includes all of the structures within the bony pelvis: from pubic symphysis to coccyx and from lateral pelvic sidewall to lateral pelvic sidewall. It thus includes not only the lower urinary tract, reproductive tract, and lower gastrointestinal tract, but the neuromuscular components of their support as well (17). In contrast to females, little information was found about the epidemiology of pelvic floor dysfunction in men and the definition of the pelvic floor in relation to pelvic floor physiotherapy in men (18).

We evaluated the validity and reliability of the PelFIS. The internal consistency of some of the scales was less than may be wished for, but we feel that from a clinical point of view some questions cannot be removed from the questionnaire, despite these items resulting in a lower alpha. This clinimetric view may seem at odds with our psychometric analysis, but these approaches have been shown to meet (19). We indeed feel that in the absence of a gold standard all means should be used that give us something to hold onto, and internal consistency can still be aimed for, with the goal of improving reliability. This should not be done by omitting clinically important items, but by adding additional items. The scales constipation and pelvic floor pain in men require attention in this sense, and items need to be added to bring alpha to a satisfactory level.

Our hypothesis that some domains are correlated supports our opinion that in case of complaints of micturition, defecation, and/or sexual dysfunction a pelvic floor questionnaire should cover all domains, to standardize history taking.

In pelvic floor physiotherapy there is no gold standard regarding the diagnostic process. This is why it is difficult to assess the sensitivity, specificity and also validity of the questionnaire. The results of this questionnaire demonstrate the need for condition- specific measures to assess the unique impact of pelvic floor dysfunction. In a future version of the PelFIs an attempt will be made to rise the α by incorporating

new items in the domains with a low α in the current version.

Through its completeness the PelFIs is likely to be a useful questionnaire for the routine clinical assessment of patients presenting to a busy pelvic floor center. At present it is being used in our own unit. The PelFIs has been translated in English and is currently being validated in English. We have added items to some of the scales for further improve of reliability. A short form of the PelFIs has been developed and will be validated in our clinic as well, not only for the use by pelvic floor physiotherapist, but also by urologists, gynecologist and surgeons.

The questionnaire, with items added as discussed, will be available upon request.

CONCLUSION

The PelFIs is a new practical and conceptually clear questionnaire that focuses on micturition, defecation and/or sexual dysfunction, related to pelvic floor dysfunction. The use of PelFIs may provide a better and reliable insight in the patients' experience of specific complaints of pelvic floor dysfunction.

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Chapter 3

How Reliable is a Self-administered Questionnaire in Detecting Sexual Abuse: a Retrospective Study in Patients with Pelvic-Floor Complaints and Review of Literature

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Introduction

Female Sexual Dysfunctions (FSDs) are very prevalent and multifaceted problems, but are under-recognized and under treated (1). Sexual abuse, a significant contributing factor to sexual dysfunction, may even be more difficult to discuss with patients than the sexual problem itself. It is of utmost importance to recognize sexual abuse because of its impact not only on gynaecological complaints but on pelvic floor complaints in general. However, there are little date available regarding the superiority of one method over another in detecting sexual abuse. We wondered if a self-administered questionnaire designed for pelvic floor complaints would be comparable in terms of suitability and reliability to a questionnaire administered by a dedicated clinician to detect sexual abuse in daily practice.

In a study of health care practitioners and gynaecologist routine screening for sexual abuse was mentioned to be rare (respectively 1, 3 and 0, 5%) (2; 3**)**

The prevalence of sexual abuse depends on the underlying definition and research population. The incidence in general population of child sexual abuse is 8-32% (4-15) in gynaecological and obstetric care 10-20% (3;14;16-18) and 19,4-27,5% in pelvic pain patients (19-21). One of the major problems in studies on sexual abuse is the lack of agreement on the definition and description of sexual abuse, like child abuse, rape or intimate partner abuse. Child abuse can be defined as any activity with a child before the age of legal consent that is for the sexual gratification of an adult or a substantially older child (22). These activities include oral-genital, genital-genital, genital-rectal, hand-genital, hand-rectal, or hand-breast contact; exposure of sexual anatomy; forced viewing of sexual anatomy; and showing pornography to a child or using a child in the production of pornography. In a recent study of Banyard et al., child sexual abuse victims reported a lifetime history of multiple exposures to various trauma and higher levels of mental health symptoms (23). The distress outcome may be diverse. Sexual violence is associated with lower rates of cervical cancer screening (24) and increased risk of posttraumatic stress disorder (PTSD) (25;26) and depression (27). Already in 1993 a good overview of the problems related to this subject was given by The Panel on Research on Child Abuse and Neglect (28).

The interest in sexual dysfunction also increases the focus on symptoms and patterns associated with sexual problems in relation to pelvic floor complaints. Klevan et al.

conclude that urinary tract symptoms following sexual abuse are common (29). In this study, 20% of the victims of sexual abuse complained of one or more genitourinary symptoms. Davilla et al. conclude that sexual abuse survivors have a significantly higher incidence of genitourinary dysfunction symptoms, including stress and urge incontinence, and voluntary urinary retention (30). In this study, 72% of the survivors of abuse reported ever experiencing urinary incontinence symptoms. Recently Jundt et al. reported significantly more women (30.6%) with overactive bladder had been previously physically and/or sexually abused than women with stress urinary incontinence (17.8%) and of the control group (17.5%) (31). Also, women with chronic pelvic pain were found to have a higher lifetime prevalence of sexual abuse (19; 32-34). The influence of early sexual abuse on later adult sexual functioning has been found to pertain in particular to problems in desire, sexual arousal and orgasm (35-37). Sarwer et al. found that childhood abuse involving sexual penetration or the use of physical force was related to adult sexual dysfunction (38). Meston et al. showed that the relationship between child sexual abuse and negative sexual affect was independent from symptoms of depression and anxiety, suggesting that the impact of child sexual abuse on sexual self-schemes may be independent from the impact that the abuse may have in other areas of the survivor's life (39). In a review article on factors predisposing women to chronic pelvic pain by Latthe et al, sexual abuse was associated with dyspareunia and also to non-cyclical pelvic pain (40).

The importance of discussing abuse before performing a gynaecological examination is clear. Survivors of sexual abuse rated the gynaecological care experience more negatively than the controls, experienced more intensely negative feelings, and reported being more uncomfortable during almost every stage of the gynaecological examination than the controls. Survivors also reported more trauma-like responses during the gynaecological examination, including overwhelming emotions, intrusive or unwanted thoughts, memories, body memories, and feelings of detachment from their bodies (41-45). In the study of Robohm et al., eighty-two percent of the survivors had never been asked about a history of sexual abuse or assault by the gynaecological care provider (41). The importance of asking about sexual abuse was clearly illustrated by Davy in relation to endoscopic procedures (46) and Schachter et al. in relation to physical therapists (47). It should be pointed out that her work refers to general physiotherapy and not pelvic floor practice, suggesting how much more relevant it is in pelvic floor physiotherapy practice.

Physicians should also consider that any kind of gynaecologic examination in these women may trigger a flashback of the primary situation and retraumatize the concerned women (48).

Our institute has recently developed and validated the Pelvic Floor Inventories Leiden (PelFIs), a 144 items new condition-specific pelvic floor assessment questionnaire, in an attempt to increase the quality of care and to get more uniformity in pelvic floor physiotherapy practice. During the validation of the PelFIs in the total population with and without pelvic floor complaints a high percentage (13, 3%) of sexual abuse was reported.

A selection of patients has been evaluated in our Pelvic Floor Center. This outpatient Pelvic Floor Center is a specialized part of our urological department and consist a surgeon, gynaecologist, urologist and a pelvic floor physiotherapist. Routinely, all new patients were sent in advance a voiding dairy and a questionnaire on pelvic floor complaints to be completed at home and discussed at the first visit of our Pelvic Floor Center. This questionnaire contains questions on defecation, lower urinary tract symptoms, obstetric information and also sexual complaints. One of the questions is about sexual abuse.

We were interested how reliable this standard self-administered questionnaire is in detecting the number of patients admitting sexual abuse.

Materials and methods

From June 2005 to August 2006 during the validation of a new administered questionnaire (PelFIs) by a pelvic floor physiotherapist 26 out of 81 patients (32%) admitted sexual abuse.

We retrospectively evaluated if these patients had visited our Pelvic Floor Center in an earlier phase. In this center a self-administered pelvic floor questionnaire is standard of care before visiting our Pelvic Floor Center. The questionnaire is sent by mail and returned by the patients on their first visit. It appeared that 20 out of 26 patients had completed this standard self-administered pelvic floor questionnaire.

The other 6 abused female patients that had completed the PelFIs were excluded because they had not been evaluated at the Pelvic Floor Center before, but had been evaluated at the department of Urology.

This self-administered questionnaire is not a validated pelvic floor questionnaire, but is used for efficiency and consists out of five parts. Part 1 contains nine questions on lower urinary tract symptoms (urgency, frequency, incontinence, urinary tract infections), part 2, four questions on gynaecological complaints (prolaps, abdominal pain, delivery); part 3, two questions on defecation, part 4, questions on medical and surgical history related to pelvic floor complaints; and part 5, four questions on sexual function (Table 1).

The PelFIs is a 144 item questionnaire administered by a pelvic floor physiotherapist and consists of six parts. Part 1 contains thirty-seven questions on general health; part 2, thirty-seven questions on lower urinary tract symptoms; part 3, thirty-three questions on defecation; part 4, nineteen questions on gynaecological complaints; part 5, nine questions on pelvic pain; and part 6 nine questions on sexual function (Table 1).

Table 1: Summary of described questions

Domain	Self-administered questionnaire	PeLFIs
Questionnaire Time	5-10 min	20-30 min
General Health	7	37
LUTS	9	37
Gynaecology/prolaps	3	19
Defecation	2	33
Pain	3	9
Sex	1. Do you have a sexual partner? (Male, Female, None) 2. Do you have sexual complaints? (Yes, No) 3. If yes, - do you experience urine lost during intercourse? (Yes, No) - do you experience pain during intercourse? (Yes, No) 4. Did you have negative sexual experience in the past? - if you would like to give a comment, you can write it underneath	1. Do you have sexual intercourse? (Yes, No) 2. Pain during intercourse? (Yes, No) 3. If yes, - during introduction of the penis - deep penetration of penis 4. Do you have sexual problems because of your pelvic floor complaint? (Yes, No) 5. If yes, - urine lost during intercourse - urine lost during orgasm - stools during intercourse 6. Did you have negative sexual experience in the past? (Yes, No) 7. If yes, did you have therapy for it? (Yes, No) 8. Can you deal with it now? (Yes, No) 9. If not, do you want therapy? (Yes, No)
Total	28	144

PeLFIs = Pelvic Floor Leiden inventories; LUTS = Lower Urinary Tract Symptoms

At our Pelvic Floor Center one physiotherapist with almost two decades of experience on pelvic floor treatment and skills in recognizing sexual abuse has been administered the PelFIs. We reviewed the self-administered questionnaires of all patients who admitted sexual abuse during the PelFIs conducted by the pelvic floor physiotherapist. Patients who experienced sexual abuse were offered sexual treatment by an urologist with a sexual education.

We tried to evaluate the reliability of the self-administered questionnaire in detecting sexual abuse using the PelFIs as "gold standard". Because both questionnaires are used routinely in our clinic we did not need institutional review board approval for this evaluation.

Results

A total of twenty patients who admitted, during administration of the PelFIs, to have sexual abuse had visited our Pelvic floor Center in an earlier phase and completed a self-administered questionnaire. At first consultation, the mean age of these 20 patients was 44, 5 year (range 19-68 years). Only 6 of them (30%) with a mean age of 50,2 year (range 38-68 years) noted in the self-administered questionnaire they did not have a history of sexual abuse, but later admitted prior sexual abuse during administration of the PelFIs. Sexual child abuse was reported in 13 out of the 20 patients; 6 patients reported a history of rape; and 1 reported intimate partner abuse. Thirteen out of the 14 patients, with a mean age 42, 1 year (range 19-63years), who completed the self-administered questionnaire described the type of sexual abuse: sexual child abuse (8), rape (4) or intimate partner abuse (1). The only patient who did not describe the kind of sexual abuse later admitted she had been the victim of sexual child abuse.

Discussion

A history of sexual abuse is a common problem in pelvic floor practice (18; 29-31; 49-56). The pelvic floor not only contains pelvic visceral organs within the pelvic

cavity; it also controls individual and integrated functions, sustains proper anatomic relationships, and shares the basic mechanism with various visceral organs that control their function. The pelvic floor is the binding element between these organs. Although pelvic floor dysfunction has long been related to the lower urinary tract and, more recently to lower gastrointestinal symptoms also, it is now considered to be an influential factor in the normal function and behaviour of the genital system in both men and women (57). Devroede described the pelvic floor as a muscular structure, pierced by the urological, genital and distal intestinal tract (58). Normal function can be replaced by dysfunctions of several kinds, overlapping voiding, sexual, genital and defecatory behaviour. He already mentioned that if the pelvic floor was not considered as an integrated muscular structure, unsuspected pathology would lie outside the spectrum of activities of the given speciality. Thus, in relation to pelvic floor complaints, it is important to evaluate sexual function in general (59), including abuse. Bachmann (60) recently published a study to obtain pilot data on physicians' knowledge, perceptions, and practices regarding FSDs, which may help uncover means of facilitating future dialog between physicians and patients. A total of 1,946 survey physicians and other health professionals used a self-administered reply questionnaire. Most respondents (60%) estimated that one- to three-quarters of their patients had FSDs. Low sexual desire was the most prevalent FSD observed. A total of 58% of participants reported initiating the first discussion of FSDs in one-quarter or less of patients. Obstacles to discuss sexual health included limited time and training, embarrassment, and absence of effective treatment options. She concluded that healthcare professionals are aware of the high prevalence of FSDs but infrequently initiate a discussion of sexual function with their female patients or fail to conduct a comprehensive evaluation for FSDs. In discussing sexual dysfunction sexual abuse is probably a more delicate topic to address.

A study of MacMillan et al about a maltreatment history in childhood using a self-administered questionnaire, concluded that child abuse may be more prevalent in younger women compared with older women, or there may be a greater willingness among younger women to report abuse (12). The women in our study who admitted abuse in the self-administered questionnaire had a mean age of 42, 1 year. The patients who did not report sexual abuse in the questionnaire had a mean age of 50, 2 year. Although the number of patients (n=20) is too small to make conclusions on age difference between the two groups. It might indicate the older the patient the less

sexual abuse is reported in a self-administered questionnaire. Marital status (in both groups 50% was married); history of psychological counselling in the past did not influence the women's decision to fill in the self-administered questionnaire.

"Did you have negative sexual experiences in the past" used in the questionnaire is of course not equal to "did you experiences sexual abuse in the past" but in the Dutch language it is considered to be almost similar. This is confirmed by the responses of patients: all patients admitted abuse and 13 out of 14 patients described the type of negative sexual experience as sexual abuse.

How forthcoming a patient is about his or her medical, sexual, and sexual abuse history may strongly be influenced by the level of comfort created by the physician taking the history. Particularly, discussing a history of sexual abuse or sexual assault with a patient is usually emotionally very difficult. This raises the question whether patients are more forthcoming when completing a self-administered questionnaire or talking to a physician. In this study 20 patients reported sexual abuse during administration of the PelFIs by a physiotherapist. 14 Out of these 20 patients (70%), completed the sexual abuse question admitting sexual abuse in the routine questionnaire before visiting our outpatient Pelvic Floor Center and talking to a physician. This high percentage of patients admitting sexual abuse during the self-administered "screening" questionnaire raises the question: "is a concerned physician needed in detecting abuse?" Or is the anonymous self-administered questionnaire avoiding a face to face contact with a physician "safer" and less embarrassing for the patient reporting sexual abuse.

This is in contrast to the conclusion of the study of Nusbaum et al describing women to be more prone to discuss sexual issues with physicians who appear to be concerned, comfortable, and informed about FSDs (61). The rate of women reporting sexual abuse to a physician varies between less than 2% (62) to 28% (63).

Although the response to the question on sexual abuse was 70% in the self-administered questionnaire compared to the administered questionnaire by a female physiotherapist, it still may be very helpful in daily practice in order to detect sexual abuse.

This raises the question if gender of the therapist influences the outcome of the study. In literature regarding this subject "the sex of the therapist" the gender of the therapist was not a major problem (64-66). Kaplan stated that: "the question of therapists' gender and its effect on therapy with women highlights an issue of therapist self-

awareness and growth rather than one of the patient's selection processes" (64). Probably, the therapist' sensitivity and value system regarding the sexual abuse issue, is the most important factor.

In general physicians cite many barriers to ask women about sexual abuse, including lack of time and resources of support, fear of offending women, lack of training, fear of opening the "Box of Pandora".

It is clear considering the impact of sexual abuse on the pelvic floor; sexual abuse is an important issue in routine pelvic floor care. However, the practice of a universal screening warrants further investigation. As Garcia-Moreno indicated it is not feasible in certain settings and may even be dangerous if caregivers lack sufficient training to ensure women's safety during and after disclosure (67).

Physicians that are uncomfortable with this topic and do not feel qualified enough to deal with the responses they might receive or observe ongoing distress in there patients should refer these women to clinicians that are familiar with these issues (68).

Essential is appropriate medical education and training in order to improve in women the identification and management of FSDs including sexual abuse, realizing we still have a long way ahead of us (60; 69-73).

We acknowledge several limitations of our study. This study relies exclusively on data of women evaluated in an outpatient Pelvic Floor Center. Moreover, it is unclear if our sample is representative for other Pelvic Floor Centers. We know that the percentage of 32% of sexual abuse is higher than was seen at our Department of Gynaecology. In a study of 325 patients at our outpatient Gynaecology Department in 1996, 15.4% reported sexual abuse and 7.4% physical molestation (74).

Also is important to mention the cultural context in which the study took place. Only patients who were able to understand and read the Dutch language could be included. This excludes a part of the non Dutch-speaking immigrants. In that matter we need more questionnaires in different language to optimizing the likelyhood of disclosure.

How forthcoming a patient is about his or her medical history, history of sexual and sexual abuse may strongly be influenced by the level of comfort provided by the physician taking the history. Our physiotherapist with almost two decades of experience on pelvic floor treatment and skills in recognizing sexual abuse has been administering the PelFIs. This could have had a positive impact on the level of detection. Also the impact of screening needs to be addressed. Screening is only possible in a setting with caregivers with sufficient sexual training. Although

screening may be a helpful tool in detecting abuse and may give both patients and physicians comfort as illustrated in the studies of Brown et al describing abuse screening in the family practice setting (75; 76).

Further research is needed to confirm our findings in other patient groups and to determine the threshold for admitting sexual abuse during interviews or self-administered questionnaires. Another important issue that needs to be addressed is the explanation of the relationship between sexual abuse and pelvic floor complaints.

Conclusion

In our opinion the interaction of a patient and clinician during the administration of a questionnaire is essential in order to gain the patients' trust and thus acquire a true perspective of past or prevalent sexual abuse and FSDs. We believe that a questionnaire administered by a clinician should be preferred to a self-administered questionnaire. However, in order to recognize sexual abuse a self-administered questionnaire can still be helpful and thus may offer healthcare physicians a helping hand in dealing with sexual abuse of their female patients in daily practice.

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Chapter 4

"Diagnostic Investigation of the Pelvic Floor": A helpful tool in the Approach in Patients with Complaints of Micturition, Defecation and/or Sexual Dysfunction.

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Introduction

The pelvic floor controls isolated and integrated functions, sustains proper anatomic relationships between pelvic visceral organs and its outlets, and shares the basic mechanism with various visceral organs that control their function (1). The pelvic floor, consisting of muscular and fascial components, is the binding element between these organs. Pelvic floor dysfunction is recognized to be related to lower urinary tract dysfunction and, more recently, to lower gastrointestinal symptoms as well (1). It is also considered to be an influential factor in dysfunction and subsequently behavior of the genital system in both men and women (1). These multisystemic functions point to the importance of caregiver awareness regarding normal pelvic floor function in general and the need for tools to diagnose specific dysfunction in patients with related symptoms.

However, literature is scarce on the topic of the diagnostic investigation of pelvic floor and there is a lack of uniformity in the description of the anatomy per se and the nomenclature of the pelvic floor (2-4). The pelvic floor comprises of several layers: from superior to inferior, the supportive connective tissue of the endopelvic fascia, the pelvic diaphragm (levator ani and coccygeus muscle), the perineal membrane (urogenital diaphragm) and the superficial layer (bulbospongiosus, ischiocavernosus and superficial transverse perineal muscles)(5). The iliococcygeus, pubococcygeus and puborectalis muscles make up the levator ani muscle of and play an important role in prevention of pelvic organ prolapse and incontinence.

The perineal membrane is a fibrous muscular layer directly below the pelvic diaphragm. The current concept is that the muscular contents of this layer are formed by the distal part of the external urethral sphincter muscle (compressor urethrae and urethrovaginalis part of the external urethral sphincter). The bulbospongiosus and ischiocavernosus muscles of the superficial layer also have a role in sexual function, while the superficial transverse perineal muscle has a supportive role.

Pelvic Floor Muscle contraction presumably involves contraction of these muscles groups.

Continence is achieved when the pressure resulting from direct action of the puborectal muscle as such and the external anal and urethral sphincters is greater than the pressure exerted on the bladder through abdominal Valsalva or bladder smooth muscle contraction (2;3;6;7). Stress urinary incontinence is the complaint of

involuntary leakage on effort or exertion, or on sneezing or coughing. Urge urinary incontinence is the complaint of involuntary leakage accompanied by or immediately preceded by urgency (8).

The assessment of the function of the pelvic floor muscles, e.g. concerning in muscle strength, tone, endurance and coordination, is difficult, because of a lack of simple to use and reliable measurement techniques, and a lack of cut-off values for pathological conditions. Furthermore, the reproducibility of testing is questionable.

Literature describes different techniques for the evaluation of pelvic floor function using transperineal ultrasound, manual muscle testing and squeeze pressure measurements (9-17). A standardization of both biofeedback technology and the methodology for its application to the pelvic floor muscle assessment and rehabilitation is also lacking (18). Kegel (19) was the first to report the efficacy of pelvic floor muscle exercises in treating urinary incontinence in women. Since then, manometric pressure measures and surface electromyography (sEMG) instrumentation have been used as a biofeedback adjunct to pelvic muscle rehabilitation. This feedback helps to isolate the specific muscles and can assist in motivation by visibly displaying pelvic floor muscle activity and progress. sEMG electrodes placed on the abdomen can help prevent the inadvertent overuse of the abdominal muscles when attempting pelvic floor contractions and help train abdominal pelvic synergy in contracting the pelvic floor muscles while experiencing intra-abdominal pressures, such as coughing(20-24). The behavioural approach of biofeedback-assisted pelvic floor rehabilitation focuses on the healthy functioning of the pelvic floor musculature which sets the tone for the whole micturition, defecation and/or sexual function process.

Before beginning therapy, specialists use various diagnostic tools such as urodynamics, a voiding diary, defecogram or even Magnetic Resonance Imaging (MRI). However, current diagnostic models have stressed the importance of a physical exam, as well as assessment of the relationship between pelvic floor function, sexual function, isolated functioning and the awareness of the relationship between structures like the bladder, rectum, anus and vagina (7, 17, 25-28). The aim of this study was, in this perspective, before starting treatment, to perform a specific diagnostic work-up focused on pelvic floor function. In our hospital, this diagnostic consultation is indicated as Diagnostic Investigation of Pelvic Floor Function (DIPFF).

Materials and Methods

Patients with complaints of micturition, defecation and/or sexual dysfunction related to pelvic floor dysfunction were retrospectively selected from the database of the Pelvic Floor Center at the Leiden University Medical Center (LUMC). We informed our medical ethical committee on this study.

Before DIPFF, all patients with complaints of micturition, defecation and/or sexual function, underwent comprehensive evaluation, including patient history, physical examination, ultra sonography of the urinary system, a voiding diary, defecogram or MRI (26, 29).

The standardized DIPFF is carried out as follows: DIPFF is done by a pelvic floor physiotherapist and starts with taking medical history using the Pelvic Floor Inventories Leiden (PelFIs) (29). The questions in the PeLFIs are related to general health, micturition and defecation and to gynaecological, obstetrical and sexual matters. The patients were asked about Quality of life and the degree of complaints for every domain using a Visual Analogue Scale (VAS). The PeLFIs questionnaire has been validated in Dutch and has been translated in English and will be validated in English. An explanation of related relevant anatomy and (patho) physiology is offered, and finally, patients are asked to perform a pad test (in case of incontinence) and to fill in a voiding diary.

A qualitative investigation of the pelvic floor function includes a qualitative physical examination of the pelvic floor function consisting of vaginal and anal visual inspection as well as digital palpation (including the Pelvic Organ Prolapse Quantification, POP-Q). Finally the pelvic floor function is assessed quantitatively by biofeedback registration.

Visual inspection

Before commencing the physical examination patients are fully informed as to what to expect during the physical examination, before starting it. An assessment is discontinued if the patient experiences any symptoms of distress during examination.

In case of complaints of micturition or vaginal prolapse, women undergo the examination in supine position. Men and women with complaints of defecation or anal prolapse are examined in lateral lithotomic position.

Inspection of the vulva, perineum and anus in women and of perineum and anus in men is performed to look for skin pathology and anatomical abnormalities. Testing for pelvic organ prolapse is an integral part of the physical examination of every patient with pelvic floor muscle complaints.

Anal/rectal or vaginal prolapse can be diagnosed by asking the patient to strain. During inspection, the patient is asked to perform one pelvic floor muscle contraction, hereby attempting to prevent the escape of gas or urine. The patient is also asked to cough.

The position of the anus and the perineum are noted at rest and during straining. In the normal situation, a pelvic floor muscle contraction will lead to ventral and cranial movement of the perineum. Extra-pelvic muscle activity is noted. Straining is classified as normal or involuntary relaxation (8).

Digital palpation

A vaginal and rectal exam is part of the investigation. In female patients the ICS POP-Q system was assessed. The POP-Q system has been developed by the International Continence Society (ICS) and was introduced in 1996. It is presently widely used for research purposes but still not yet broadly introduced in clinical practice. In the POP-Q system, nine well defined points and distances are measured: two points of the anterior compartment (Aa and Ba), two points in the middle compartment (C and D) and two points of the posterior compartment (Ap and Bp). These six points are measured during maximal protrusion of the prolapse and are measured in relation to the hymen. Three additional distances are measured: the perineal body (PB), genital hiatus (GH), and the total vaginal length (TVL). The nine measurements are the basis for a five point ordinal staging from stage 0 (no prolapse at all) till stage 4 (complete eversion of the vagina) (30, 31).

Digital vaginal palpation is performed with one (index) finger because two fingers may stretch the pelvic floor muscles and thereby influence the ability to contract. For anal palpation, the patient is put in left lateral position, for vaginal palpation the patient is put in supine position with one pillow under the head, hips and knees flexed to 60°.

Digital palpation is performed to assess qualitatively the pelvic floor muscles and surrounding areas at rest, during contraction and relaxation. The pelvic floor and related muscles, like the external and internal anal sphincter, the puborectal muscle

and the levator ani are palpated circumferentially based on the anatomy. Digital palpation is also used to test for pain and sensitivity of the palpated areas. Digital pressure on the pelvic floor muscles may reproduce or intensify the patient's pain. This sign of pain can be unilateral. The patient is asked to contract and to relax the pelvic floor muscles 10 times. After one minute rest the patient is asked to contract the pelvic floor muscles for 10 seconds, 5 times with one minute rest between. The patients are asked to prevent the escape of urine or gas, to cough and to strain .The quality of the contractions and relaxation is described according to ICS –protocol of ICS terminology procedure (8).

The quantification of a contraction is problematic. There is no validated scale to quantify contractions of the pelvic floor muscles. Therefore quantification, more specific than absent, weak, normal, or strong is not recommended.

EMG

The quantitative investigation of the pelvic floor function consists of EMG registration of the behaviour of the pelvic floor during an identical sequence of tests as described above. Sex-dependent differences are visible in all three planes. Because of the absence of (inter)nationally accepted reference values we defined in women, based on our experience for 18 years, a muscle tone at rest of 1-2 microvolt (μV) as normal and a rest tone above 2 μV as an elevated rest tone. In men the normal rest tone of the pelvic floor is about 2-3 μV.

Because of the clear difference in male and female anatomy, different electrodes are needed in the treatment of pelvic floor dysfunction (11; 32). The Myomed 932® (Enraf Nonius, Delft, the Netherlands) was used for biofeedback registration with a vaginal probe (EMG, 2 rings vaginal probe 2 mm, V.M.P.Bioparç, Auriol, France) or an EMG anal probe (2 rings anal probe 2 mm, V.M.P.Bioparc, Auriol, France). The vaginal probe is inserted up to the thinnest part, at the level of the introitus and the anal probe is inserted with the proximal bulge at the anal verge (33). During a voluntary contraction of the pelvic floor muscles, the intensity of the EMG signal should increase.

When the patient is asked to hold the contraction, a sustained high intensity on the EMG can be observed. At subsequent relaxation, the EMG intensity will fall to baseline or even below. First, the muscle tone at rest is registered during one minute. Then the patient is asked to make 10 voluntary contractions (fast twitch), each lasting

3 seconds, followed by relaxation. A voluntary relaxation after a contraction indicates that the patient is able to relax the pelvic floor muscles on demand. The pelvic floor will return to its resting state. After 1 minute rest the subjects are asked to perform a sustained contraction, resulting in a ventral and cranial movement of the pelvic floor muscles. They should try to hold the contraction for as long as possible up to a maximum of 30 seconds (slow twitch). The patients are asked to continue breathing as normal as possible during the pelvic floor muscle contraction.

Finally, the straining potential is investigated. We instruct the patients to strain as if they are defecating. In our institute the results of this straining are classified as normal or paradoxal behaviour of the pelvic floor.

Results

238 Patients with complaints of micturition, defecation and/or sexual function were included in this study, analysed at the Pelvic Floor Center of the Leiden University Medical Center (July 2004 and July 2006): 97 men with a mean age of 52 years (12-91 years) and 141 women with a mean age of 47 years (18-79 years). In total 134 patients (56.3 %) underwent surgery for their complaints before DIPFF: in 54 men (41%) and 80 women (59%). In our patient population there was a considerable amount of sexual abuse in women and men as assessed by the PelFIs (Table1).

Table 1: Patient Characteristics.

History	Men N=97	Women N=141	Total N=238
Age (years)	52 (12-91)	47 (18-79)	50 (12-91)
Surgery (%)	41	59	56.3
Sexual abuse (%)	14.4	32.0	24.8

Based on the referral diagnosis 224 patients (94.1%) had complaints of micturition, 199 of defecation (82.7%) and 154 on sexuality (64.7%, PelFIs). However, stratification of patients according to their complaints at first visit results in 3 subgroups: patients with one single complaint (micturation, defecation or sexual), a combination of two complaints or complaints in all compartments of the pelvic floor (Table 2).

Table 2. Complaints of patients

Complaints (%)	Men N=97	Women* N=141	Total N=238
Micturation	91.1	96.2	94.1
Defecation	86.1	80.2	82.7
Sexual	63.5	65.7	65.2
One compartment of pelvic floor	10.3	14.2	12.6
Two compartments of pelvic floor	40.2	24.8	31.1
Three compartments of pelvic floor	49.5	60.3	55.9

* *One woman became free of complaints on the waiting list*

In the total group 34 patients (14.3%) used medication for micturation during their first visit, 20 for defecation (8.4%) and 4 for sexual dysfunction (1.7 %, men only). A total of 16 patients (6.7%) used anti depressants: 7 men (7.2%) and 9 women (6.4%) (Table 3).

Table 3. Medication.

Medication (%)	Men N= 97	Women N= 141	Total N= 238
Micturition	16.5	12.8	14.3
Defecation	8.2	8.5	8.4
Sexual function	4.1	0.0	1.7
Anti depressants	7.2	6.48	6.7

The mean rest tone of the pelvic floor was 5 μV in men (0.0-12.0 μV) and 3.8 μV in women (0.5-16.0 μV). Based on our definition a normal rest tone, an elevated rest tone of the pelvic floor was found in 141 patients (69.3 %): 79 men (81.4 %) and 86 women (61.0 %). In patients with complaints of micturation an elevated rest tone was found in 69.2 % (70 men and 85 women), with complaints of defecation in 72.4 % (68 men and 76 women) and with sexual dysfunction in 74 % (53 men and 61 women).

A history of sexual abuse as assessed by the PeLFIs questionnaire was documented in 59 patients (24, 8 %): in 14 men (14.4%) and in 45 women (32.0%). This gender difference in sexual abuse was significant ($p = 0.002$). The mean age of women with a history of sexual abuse was 45.5 years and in men 51.6 years.

In the group of patients with a history of sexual abuse 47 patients (80.0%) were found to have an overactive rest tone of the pelvic floor: 13 men (92.9 %) and 34 women (75.6 %) (Table 4)

Table 4: Biofeedback registration comparing men and women.

Biofeedback	Total N = 238	Men N = 97	Women N = 141
Resttone (µV)	4.4 (0-16.0)	5.0 (0.0-12.0)	3.9 (0.5-16.0)
Fast twitch (µV)	11.3 (0.0-30.0)	14. 1 (0.0-30.0)	9.3 (0.5- 30.0)
Slow twitch (µV)	8.8 (0.0-30.0)	10.8 (0.0-30.0)	7.4 (0.0-30.0)
Ivoluntary relaxation (%)	77.3	81.4	74.7
Elevated rest tone (%)	69.3	81.4	61.0

Discussion

The lower urinary tract, the anorectal channel and the internal genitals as well as the pelvic floor are closely related to each other, both anatomically and, what is becoming more and more apparant, functionally. Hence, it is mandatory in patients with complaints of micturition, defecation and/or sexual dysfunction to take into account the function of all these organs including the pelvic floor rather than focusing on isolated organs. This is true for history taking, diagnostic investigations and treatment. The Dutch Urological Association states in its guidelines that, in cases of urge and stress urinary incontinence and urgency/frequency, pelvic floor physiotherapy is a first choice treatment option. An overactive bladder (OAB), with or without in continence, negatively affects women's sexual health, reducing sexual desire and ability to archieve orgasm. Given the impact of OAB on sexual health, sexual health should be routinely assessed by clinicians and addressed by researchers (34). In this respect, it does not make sense that medical specialists focus their diagnostic attention

to the bladder, rectal, anal and/or sexual function solely. Attention should be focused on the DIPFF.

Another issue hampering the research of pelvic floor dysfunction is the total lack of standardization of both biofeedback technology and the methodology for its application to pelvic floor muscle assessment and rehabilitation. Both the small number of studies and this lack of standardized technology and protocols are limiting factors in generalizing our findings. It is also of note that to date, the mechanisms responsible for therapeutic efficacy have not been clarified beyond doubt. Pelvic floor muscle biofeedback is effective in the treatment of urinary incontinence. In the majority of studies, biofeedback is statistically superior to comparable treatments and controls; moreover no study was superior to biofeedback (11).

Also, elctrostimulation (ES) was found to be a safe and effective theraoy in women with sexual dysfunction. The lack of controlled parameters has made it difficult to evaluate the true efficacy of intravagianal ES. Moreover the stimualtion equipments as well as the treatment regimens are not standardized, and it is difficult to draw conclusions about electrical parameters of frequency, pulse duration, pulse-to-rest ratio, length of treatment, power and accurate success rates (36).

The nomenclature of the ICS does not define the rest tone of the pelvic floor and no reference values are available (8). In literature protocols of biofeedback showed a wide variation in descriptions on patient education, contraction parameters, numbers of training sessions, numbers of repetitions, duration of training, use of accessory muscles, patient positioning, etc. (11).

Using our definition of the normal rest tone we were impressed by the number of patients with an elevated rest tone of the pelvic floor. Remarkable as well was the high prevalence of patients with a history of sexual abuse (24.8 %: men 14.4%, women 32.0%).

Being a referral center sexual dysfunctions are presented as quite prevalent and multifaceted problems, but they are continuously underrecognized and undertreated in mixed patient populations (37). Pelvic-floor complaints are correlated with sexual abuse and asking about abuse should be a routine part of screening as well. Considering the fact that many practitioners have difficulty enquiring about abuse, we have suggested earlier that a questionnaire may be helpful in improving the recognition and management of patients who have a history of sexual abuse.

In our center the use of these questionnaires is standard of care (38, 39).

In contrast to our population the frequency of sexual abuse was mentioned to be rare on routine screening for sexual abuse by health care practitioners and gynaecologists (respectively 1.3 and 0.5%) (37, 40).

In relation to the technique of pelvic floor investigation placement and design of probes are relevant in pelvic floor dysfunction (33) and the resulting rest tone measurements may vary depending on the type of probe used, the placement of the probe and used equipment. To our knowledge there is no means of calibrating the different types of probes and equipment used in pelvic floor practice. Furthermore, literature provides scarce knowledge and consensus on treatment of an elevated pelvic floor rest tone.

In the standardization on terminology of pelvic floor dysfunction by the ICS it is stated that overactivity of pelvic floor muscles is a situation in which the pelvic floor muscles do not relax, or even may contract when relaxation is functionally needed for example during micturition or defecation. This condition is based on symptoms such as voiding difficulty, obstructed defecation, or dyspareunia and on signs like the absence of voluntary pelvic floor muscle relaxation.

In daily practice this definition is not sufficient to explain the findings in patients. We feel it is important to be able to differentiate between the activities of the pelvic floor in terms of relax capacity and contract capacity. We believe that the elevated rest tone is related to symptoms as mentioned in the ICS definition and not the activity of the pelvic floor as such.

Although we describe a relationship between an elevated rest tone and a dysfunction of the bladder, vagina and/or rectum, the exact mechanism of this relationship remains unclear. However, we are convinced that in order to break through the vicious circle of an elevated rest tone, treatment should be focused on pelvic floor relaxation instead of straining (“pelvic floor exercises”) (11;33;41, 42).

Based on this conviction, we recommend an individual assessment of patients rather than treatment solely based on complaints. In case of an elevated rest tone, the the primary target is relaxation and restoration of the coordination of pelvic floor muscles (43). In contrast, when a weakness of the pelvic floor is diagnosed, the primary target is strengthening and training of the endurance of the pelvic floor. Biofeedback therapy is known to be effective in conditions as mentioned above (13, 27, 33, 4244, 45)

The DIPFF may be a helpful diagnostic tool, but further randomized controlled studies are necessary to validate this intervation.

Conclusion

Pelvic floor dysfunction is correlated with urinary, sexual or gastroenterological complaints. In our retrospective study we found that 77, 2 % of patients who presented to the clinic with urinary, gastro or sexual complaints had measurable pelvic floor dysfunction (69, 3 % overactive rest tone and 7, 9 % under active rest tone). In relation to the ICS terminology there is a need for a well defined normal versus elevated rest tone of the pelvic floor.

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Chapter 5

Placement of probes in electro stimulation and biofeedback training in pelvic floor dysfunction

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Introduction

Since the introduction of the manometric probe used as a perineometer by Kegel (1), many electrodes have been developed for intravaginal and intra-anal electrostimulation and biofeedback training in the treatment of pelvic floor dysfunction. Intravaginal and intra-anal electrostimulation and biofeedback training are used for treatment of urinary urge- and stress incontinence, anal dysfunction, and sexual dysfunction. For optimal treatment, knowledge of the structures that are the main targets in stimulating and in biofeedback training is needed. This knowledge of both the anatomy of the pelvic floor and physiological aspects should result in optimal design of probes. However, lack of uniformity in description of the anatomy per se, the nomenclature of the pelvic floor (2-4), and stimulation techniques is hampering such a design (5–8). Moreover, the available, commonly used probes have been developed empirically.

Based on the present knowledge, the pelvic floor basically comprises the levator ani and the puborectal muscle. Pelvic floor muscle contraction presumably involves contraction of these two muscles (9). The levator ani is a muscle active in the process of evacuation (9–11). On contraction it facilitates the process of defecation and micturition. In contrast, the puborectal muscle is a muscle active in the process of continence. The puborectal muscle is a vertically lying U-shaped sling embracing the urethra and anal canal. Furthermore, the external anal and urethral sphincters originate in the puborectal muscle (11–14). During puborectal muscle contraction, the two sphincters contract synchronously, resulting in a closure (‘sealing’) of the urethra and anal canal (15). Continence, in short, is a result of the direct action of the puborectal muscle per se and the external anal and urethral sphincters.

In sphincter/stress incontinence, enforcement of the external sphincters, and/or pelvic floor musculature, the puborectal muscle is, in our opinion, the main target of electrostimulation. However the primary targets are not the muscles but the pelvic and/or pudendal nerve fibers. Those fibers directly activated by electrostimulation indirectly induce activity of the muscles.

In urge incontinence, two modes of action are described: stimulation of pudendal nerve afferents, resulting in detrusor inhibition through central reflexes, as well as stimulation of efferents resulting in enhancement of pelvic floor and urethral sphincter musculature tone, inducing detrusor inhibition through the guarding reflex (5). As these modes of action are quite different, with different targets, it is questionable whether the demands for optimal probes are uniform. It is more likely that various types of probes are needed for optimal stimulation-treatment as well as for biofeedback registration.

This investigation was performed in order to validate the anatomical positioning of commonly used commercially available probes, positioned according to standard protocol as used in daily practice by pelvic floor physiotherapists. This study was performed preliminarily to a larger study in order to construct a probe optimized for structures we want to stimulate and registration in pelvic floor treatment.

Material and methods

To investigate the positioning of the anal and vaginal probes, we used the Aloka® SSD 1700 Ultrasound, the power Doppler and the Falcon Ultrasound scanner Type 2101 from Bruel-Kjaer Medical®, with transducer type 8658/S and 1850, to localize musculature and the neurovascular bundle of the pelvic floor. The transducer 8658/S was used in combination with the Brachy balloon from Barzell-Whitmore Maroon Bells®. The anatomy of the pelvic floor was investigated in detail using the 0.5-T MRI scanner (Philips NT5, Philips Medical Systems®, Best, the Netherlands) equipped with an endoanal coil. We performed a thorough literature review on pelvic floor anatomy and placements of probes in pelvic floor physiotherapy.

We evaluated the optimal placement of probes in two healthy multiparous women, without pelvic floor dysfunction. The distance from the recording rings to the muscles is described at the proximal parts of the puborectal muscle and the anal external sphincter. Positioning of the anal probes was examined in left lateral decubitis position, with the ultrasound transducer introduced in the vagina. The positioning of the vaginal probes was examined in lithotomic position with the ultrasound transducer

in the anal canal. The anatomy was compared with a vast number of MRI examinations performed with an endoanal coil according to protocol in our institute.

During the examination the women were asked to strain and to bear down. Repeated measures were performed on both subjects with a time interval of three weeks. The time elapsed between using each test probe was 15 min and we requested both women to do 10 fast twitch contractions and 5 slow twitch contractions. Five probes, 3 vaginal and 2 anal, were tested and technically described. Three probes have longitudinal recording plates and two have concentric recording plates (Table I).

Table 1. Description of investigated probes (Prm = puborectal muscle; numbers are expressed in centimeters)

Type of probes	Probe 1. Neen, vaginal	Probe 2. Veriprobe, vaginal	Probe 3. EMG, vaginal	Probe 4. Neen, anuform	Probe 5. EMG, anal
Shape of recording plates	Longitudinal	Longitudinal, rectangle	Concentric	Longitudinal, trapezoid	Concentric
Length of recording plates	3.5	3.5	–	2.7	–
Width of recording plates	1.5	2.0	1.0	0.5–1.0	0.5
Circumference of probe	10.0	8.2	7.7	7.0	5.0
Length of probe	7.5	8.8	12.7	8.4	13.6
Place of insertion	Introitus	Introitus	Introitus	Anal verge	Anal verge
Position of recording plates in relation to puborectal muscle	3 cm cranial of prm	At prm	6 cm cranial of prm	1 cm caudal of prm	2 cm cranial of prm

Neen, vaginal probe, Verity Medical Ltd® (Figure 1, probe 1)

This probe has a total length of 7.5 cm and a circumference of 10 cm. It has two longitudinal recording plates. The distance between the top of the probe and both recording plates is 1.5 cm. The two recording plates are situated alongside the body of the probe and are 1.5 cm wide and 3.5 cm long. The distance of the base of the probe to both recording plates is 3.0 cm. The probe is inserted into the vagina, up to the ring at the introitus.

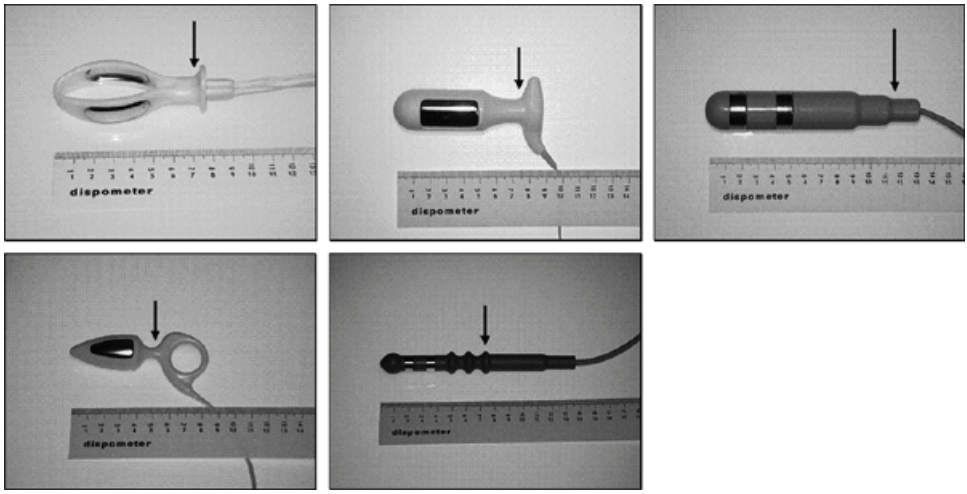

Figure 1. Probes (1–5); all probes were inserted up to the arrow, length of probe in cm. Probe 1: Neen, vaginal probe, periform. Probe 2: Veriprobe, vaginal probe. Probe 3: EMG, 2-ring vaginal probe 2 mm. Probe 4: Neen, anal probe, anuform. Probe 5: EMG, 2-ring anal probe 2 mm.

Veriprobe, vaginal probe with longitudinal plates, Verity Medical Ltd® (Figure 1, probe 2)

This probe has a total length of 8.8 cm and a circumference of 8.2 cm. Two longitudinal rectangle-shaped recording plates are situated alongside the body of the probe and are 2.0 cm wide and 3.5 cm long, and are flush with the body of the probe. The distance between the two recording plates is 2.0 cm. The distance of the recording plate to the top is 1.5

cm, to the bottom 2.1 cm. The external part of the probe is 1.3 cm long. This probe is inserted up to the handle at the introitus.

EMG, 2-ring vaginal probe 2 mm, V.M.P. Bioparc® (Figure 1, probe 3)

This probe has two circular recording plates. The total length of this probe is 12.7 cm, the circumference 7.7 cm. The distance from the top ring to the top of the probe is 1.4 cm. The distance between the two rings is 1.8 cm and the width of both rings is 1.0 cm. This probe is inserted up to the thinnest part, at the level of the introitus.

Neen, anal probe, anuform, Verity Medical Ltd® (Figure 1, probe 4)

This probe has a total length of 8.4 cm and a maximal circumference of 7.0 cm. It consists of a body, with two longitudinal recording plates, a neck and an open ring. The recording plates are trapezoid like. The distal side of the recording plate is 0.5 cm wide, the proximal side 1.0 cm. The length of the recording plate is 2.7 cm. The distance between the two recording plates is about 2.0 cm. The distance of the recording plate to the top of the probe is 1.0 cm, to the base 0.5 cm. The length of the ring is 3.0 cm. This probe is inserted with the ring up to the anal verge.

EMG, 2-ring anal probe 2 mm, V.M.P. Bioparc® (Figure 1, probe 5)

This probe has two circular recording plates. The probe has a total length of 13.6 cm. The circumference of the top of the probe is 5.0 cm. The distance from the distal recording ring to the top is 1.8 cm. The distance between the two rings is 1.0 cm. The width of both rings is 0.5 cm. The distance from the proximal ring to the next bulge is 1.0 cm. There are three bulges with two gaps of 1.0 cm in between. These bulges are for the purpose of fixation. The distance from the proximal bulge to the base of the probe is 6.0 cm. This probe is inserted with the proximal bulge at the anal verge.

Results

Ultrasonography was used to document relevant anatomical structures in both women: first, at 0.5 cm of the anal verge, the anal external sphincter is visualized with a width of about 2.5 cm. The fibers of this muscle are confluent with the fibers of the puborectal muscle cranially. The width of the puborectal muscle is 2.5 cm. Surrounded by these muscles, the internal anal sphincter together with circular and longitudinal layers of the rectum are pictured (Figure 2). The levator ani is positioned above the puborectal muscle, as a dome from left to right (Figures 2 and 4). The urethral external sphincter could not be visualized.

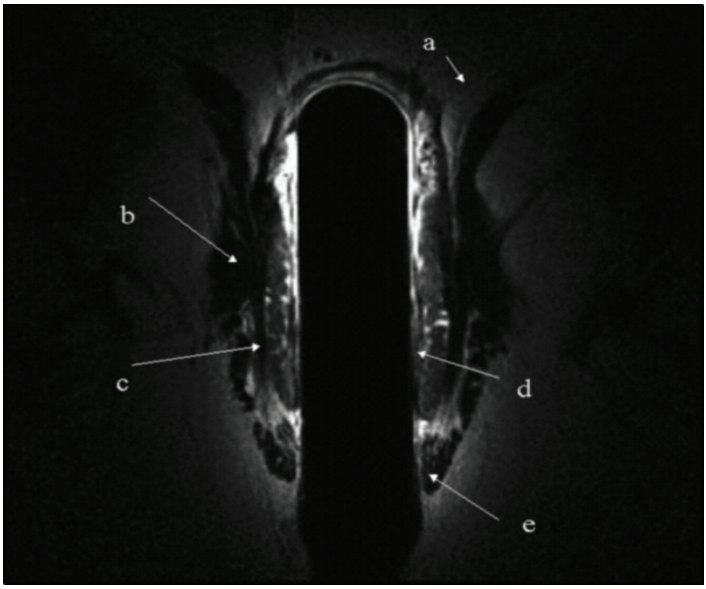

Figure 2. MRI of the anorectal canal with the anal rectal coil. (a) levator ani, (b) puborectal muscle, (c) anal internal sphincter, (d) longitudinal layers of the rectum, (e) anal external sphincter. From caudal to cranial the anal external sphincter is visualized first. The fibers of this muscle turn into the fibers of the puborectal muscle cranially. Encircled by these muscles is the internal anal sphincter together with the circular and longitudinal layers of the rectum.

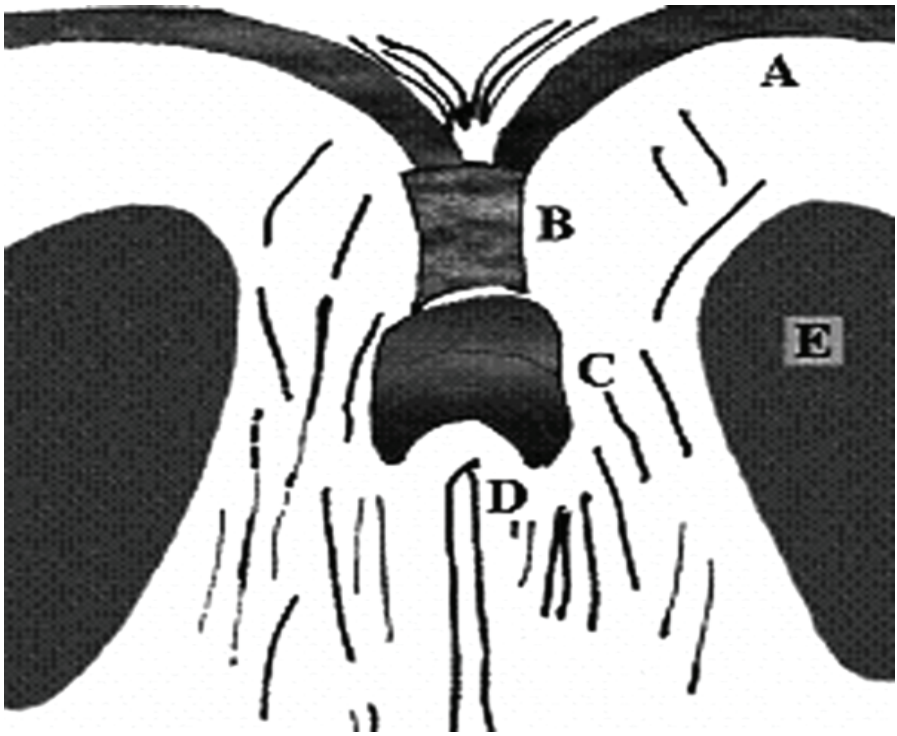

Figure 4: Pelvic floor anatomy. The anal external sphincter (C) is visualized first. The fibers of this muscle turn into the fibers of the puborectal muscle (B) cranially. Encircled by these muscles is the anal internal sphincter together with the circular and longitudinal layers of the rectum. The levator ani (A) is positioned above the puborectal muscle, as a dome from the left to the right. Other structures demonstrated in the figure are the anus (D) and the pelvic bone (E). Adapted from Hussain (17).

Neen vaginal probe, periform

At proper placement, the recording plates are located 3 cm cranial of the distal edge of the puborectal muscle. The bulk of this probe will take its natural place within the vagina and the vaginal wall is pushed aside gently together with the puborectal muscle.

Veriprobe, vaginal probe

Both plates were close to the puborectal muscle, 2.5 cm cranial of the anal external sphincter both in rest and during straining. While straining the probe slipped out of the vagina. Due to the size of the probe the vaginal wall with the puborectal muscle is pushed aside gently.

EMG, 2-ring vaginal probe 2 mm

On endo ultrasonography we visualized the proximal electrode 6 cm cranial of the puborectal muscle. The distal electrode was positioned against the bladder wall.

Neen probe, anuform

The recording plates are located next to the anal external sphincter, 1 cm caudal of the puborectal muscle. Because of the configuration and the size of the probe, the probe fits naturally in the anorectal canal. On contracting both the anal external sphincter and the puborectal muscle pushed the probe upwards into the rectum. Due to the size of the probe the rectal wall as well as the puborectal muscle is pushed aside gently.

EMG, 2-ring anal probe

With the probe positioned as described, with the proximal bulge at the anal verge, the electrodes were positioned 2 cm cranial of the puborectal muscle and 4 cm cranial of the anal external sphincter. When the probe was inserted less deep with the proximal bulge outside the anus, the plates were located near the puborectal muscle. If the probe is positioned even less deep with the distal bulge at the level of the anal verge, the distal ring of the electrode was exactly at the puborectal muscle and the proximal ring at the anal external sphincter (Figure 3).

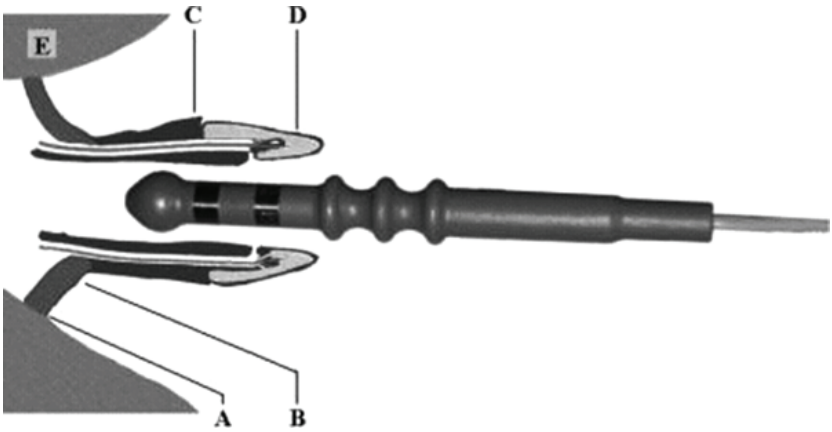

Figure 3. Pelvic floor anatomy. The EMG probe anal, 2 rings, is positioned with the distal electrode at the puborectal muscle (C) and the proximal electrode at the anal external sphincter (D). Other structures demonstrated in the figure are arcus tendineus (A) and the levator ani (B) relative close to the pelvic bone (E). Adapted from Hussain (17).

Discussion

The literature on this topic is scarce. The commercially available probes studied vary in design that is in shape and size of the body of the probe and in type of recording electrodes (plates or rings). Notwithstanding, they all have the same purpose: proper placement during treatment of pelvic floor dysfunction. What proper placement means depends on the structures that need to be stimulated or registered (nerves, external sphincters, puborectal muscle, or other pelvic floor muscles). The muscular anatomy can be described as consisting of, roughly speaking, 3 layers of muscles: from caudal to cranial: the anal external sphincter, the puborectal muscle, and the levator group. The results of the measurements of the vaginal electrodes vary from close to the puborectal muscle (Veriprobe) to 6cm cranial of the puborectal muscle (EMG 2-ring vaginal probe 2mm). The anal electrodes vary from next to the anal external sphincter, 1cm caudal of

the puborectal muscle (Neen probe, anuform), to 2 cm cranial of the puborectal muscle and 4cm cranial at the anal external sphincter (EMG probe anal, 2 rings). Measurements were reproducible in each subject and for each probe, independently of the sequence. Readings of the probe were not influenced by the presence or absence of the ultrasound probe in the adjacent orifice.

In case of electrostimulation for treatment of urinary urge incontinence, stimulating should be focused on afferent nerve fibers of the plexus pelvicus and the pudendal nerve (5) or, if the guarding reflex is involved as well, as in case of stress incontinence, on the external sphincter and pelvic floor musculature. It is assumed that, in this respect, of all pelvic floor muscles, the puborectal muscle is the most relevant one (15). Using electrostimulation in cases of fecal incontinence, the focus is on the anal external sphincter as well as on the puborectal muscle. In biofeedback training we aim to record the function of the urethral and anal sphincters and the puborectal muscle. This means that for biofeedback training a close relation between the electrode plates and the muscle itself is important. However, in cases of electrostimulation of pelvic floor dysfunction (stress and urge incontinence, fecal incontinence, and obstructed defecation), stimulation of afferent and/or efferent nerves is mandatory and not necessarily direct stimulation of the involved muscles. The general requirement to obtain an effect of electrical stimulation is that the intensity of stimulation is sufficient to elicit impulses in a relevant nerve. The threshold intensity to evoke a response in the muscles varies inversely with the nerve fiber diameter, the distance between the nerve and the size of the stimulating electrode, and the pulse configuration. All tested probes had a large electrode area. The effect of this is that a relatively large current is needed to elicit an effect, but this is not by itself harmful. If the electrodes are not positioned at the anal external sphincter and/or the puborectal muscle, we assume that in biofeedback training we are in fact registering a composite EMG signal of the total area, not only the pelvic floor, but the sum of all active surrounding muscles as well as the response to intra-abdominal pressure.

Based on our findings we conclude that the electrodes of the probes, as we use them now during electrostimulation and biofeedback training in the treatment of pelvic floor dysfunction, are not optimal for the structures we want to stimulate or to register.

Observation of the anal positioning of the probe by vaginal ultrasound demonstrated that during an attempt to perform a pelvic floor contraction, the anal external sphincter 'rolls' backwards, taking the shape of a 'drop'. Simultaneously the urethra stretches itself, elongates and is pulled down during contracting the urethral sphincter and the puborectal muscle. In contrast, during straining, the urethra is shortened and moves upwards.

Optimal probe fitting may be even more complex. According to Hussain (16), sex-dependent differences are visible in all three planes. Because of the clear difference in male and female anatomy, different electrodes are needed in the treatment of pelvic floor dysfunction.

Ultrasound and MRI imaging demonstrated that the positioning of the electrodes is close to the plexus pelvicus. Besides stimulation of afferent or efferent, motoric nerves, the mode of action of intravaginal stimulation for urge incontinence may also be related to direct stimulation of the bladder wall or the urethra. If we position the electrodes at the anal external sphincter or in the anal canal below the linea dentata, or just behind the vaginal introitus, electrostimulation is far too painful for the patient. Direct stimulation of skin and mucosa, also at lower intensity, is probably the cause of this pain sensation. In case of biofeedback, the optimal position of the probes for stimulation is quite different.

In our opinion the ideal probe must be:

1. registering;
    - vaginal: the puborectal muscle, the external urethral sphincter;
    - anal: the puborectal muscle, the anal external sphincter, the levator ani
2. stimulating the structures we want to stimulate: nerves or muscles
3. shaped and sized adapted to the local anatomy (not vice versa)
4. comfortable for the patient
5. maintaining its position
6. the reference electrode should be incorporated
7. suitable for sterilization
8. durable
9. containing rings and plates.

Conclusions

As the five examined commercially available probes vary considerably in their relationship with the, roughly speaking, three layers of muscles, it is unlikely that they are all fit for optimal use.

In our opinion, the anal and vaginal probes we use presently have a too large diameter, even in women after vaginal delivery. In view of our findings we are now re-evaluating the normal anatomy and physiology of the pelvic floor and the anatomy in men and women with pelvic floor dysfunction. Studies to determine the primary anatomical and

physiological focus for both vaginal or anal electrostimulation and feedback will be conducted at our institute in order to meet the demand for optimized probes.

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Chapter 6

Effects of magnetic stimulation in the treatment of pelvic floor dysfunction

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Introduction

Pelvic floor dysfunction is primarily managed by behavioural or pharmacological treatment. The Dutch Urological Association states in its guidelines that, in cases of urge and stress urinary incontinence and urgency/frequency, pelvic floor physiotherapy is the treatment of first choice.

Except in very specific cases, surgery should only be considered after behavioural and pharmacological interventions have been tried (1). Dysfunction of the pelvic organs can be treated by biofeedback training, electrical stimulation and pelvic floor muscle exercises. Quantification of the function of the pelvic floor muscles is not easy, because of the lack of simple and reliable measurement techniques and the lack of threshold values for pathological conditions. Furthermore, the reproducibility of testing is questionable. Strengthening the pelvic floor musculature as developed by Kegel (2) popularized nonsurgical treatment for stress urinary incontinence, and since then, various other rehabilitative techniques were introduced. Biofeedback training allows a more selective control of the pelvic floor musculature, resulting in a reduction in micturition, defecation or sexual symptoms (3). Electrical stimulation of the pelvic floor was reported to be an effective alternative treatment (4), and there are several different techniques, e.g. intra-anal or vaginal stimulation, tibial nerve stimulation (5) and sacral nerve stimulation (6).

Extracorporeal magnetic innervation therapy (ExMI) is a more recent technique (7–9) that uses a classic principle of physics. Faraday's law of magnetic induction states that a current will flow in a conducting medium in response to a changing magnetic field, and ExMI uses this to induce a controlled depolarization of adjacent nerves and subsequent muscle contraction. Published results vary from a >50% improvement in 69% of patients, including 44% dry at 2 weeks, to objective improvement in 58% of patients. Magnetic stimulation was developed to stimulate the central and peripheral nervous system noninvasively. A varying magnetic field will induce an electrical field in any specified loop in its vicinity (10). The roots of sacral nerves S2–S4 provide the primary autonomic and somatic innervation of the lower urinary tract, including the pelvic floor, urethra,

bladder, vagina wall and rectum, and stimulation of these roots is an efficient way to modulate the pelvic floor and subsequently control the pelvic organs (11). In sphincter stress incontinence, the ultimate target of electrostimulation is to reinforce the external sphincters and/or pelvic floor muscles, but the actual primary targets are the pelvic and/or pudendal nerves. In urge incontinence, two modes of action have been described: stimulation of pudendal nerve afferents, which results in detrusor inhibition via central reflexes, and stimulation of efferents, which results in enhancement of pelvic floor and urethral sphincter musculature tone, inducing detrusor inhibition via the guarding reflex (12). Hence, it is important to correlate the clinical results of this treatment with functional changes in the pelvic floor musculature.

In the present pilot study we evaluated the effects of ExMI, focusing on these correlations to assess whether ExMI is suitable for our patients.

Material and Methods

From July 2002, 74 patients (65 women and nine men) with urge incontinence, urgency/frequency, stress incontinence, mixed incontinence and defecation problems were included in a prospective study of the electromagnetic chair (Neocontrol®, Neotonus, Marietta, GA, USA). Patients with a history of radiotherapy, a pacemaker or other metal implants, as well as concurrent pregnancy, malignancy or physiotherapy during the study, were excluded.

During treatment, the patients sat on the electromagnetic chair; stimulation was provided by an electromagnetic generator in the seat, and was controlled by an external unit. The generator creates pulses of 275 μs. The chair is operated by patients using programmed prescription cards. The physiotherapist or clinician can control the magnetic field by adjusting the frequency and amplitude of stimulation. The amplitude determines the volume of the field, and thus whether it is strong enough to induce a nerve impulse. The magnetic coil is integrated in the seat; the effect is greatest at the centre of the field, so the perineum must be in the middle of the seat. The stimulus intensity was gradually increased up to the limit of tolerability as indicated by the patient (average 80–100% of

the maximum). The control unit displays the status, the pulse generation and the possibility for external communication via a modem.

All patients were treated twice a week for 8 weeks. Previous studies showed that a stimulation frequency of 10 Hz was most effective for inducing bladder inhibition, and 50 Hz was most effective for urethral closure (13). At each treatment session, we treated patients with urge incontinence for two episodes of 10 min at 10 Hz, with an interval of 1 min. Patients with stress incontinence were treated for two episodes of 10 min at 50 Hz, with a interval of 1 min. Patients with mixed incontinence were treated for 10 min at 10 Hz and for 10 min at 50 Hz.

For urodynamic evaluation, UD-200 equipment (Medical Measurement Systems, Enschede, the Netherlands) and MMS Unitip catheter with one urethral and one bladder sensor were used, at baseline and after completing the study. Digital palpation and electromyography (EMG) registration (Myomed 932® equipment, Enraf Nonius, Delft, the Netherlands) with a vaginal (EMG, two rings vaginal probe 2 mm, V.M.P. Bioparc®) or anal probe (EMG, two rings anal probe 2 mm, V.M.P. Bioparc), at baseline and after completing the study (1 week after the last treatment), were used to document pelvic floor function. During palpation and registration we evaluated the basal amplitude registered on EMG, the voluntary or involuntary contraction, a voluntary or involuntary relaxation of the pelvic floor, and whether the pelvic floor was not contracting, not relaxing or not functioning (14). A voiding diary, a pad-test (15), King's Health Questionnaire (KHQ) (16,17) and a visual analogue scale (VAS) were completed at baseline and at the end of the study (1 week after the last treatment) to evaluate voiding patterns and quality of life (QoL). The medical history and previous treatments were documented (drugs, physiotherapy, electrotherapy, Stoller Afferent Nerve Stimulation, or a combination of therapies). The therapy was considered successful if incontinent episodes or voiding frequency decreased by half or more. The range for 'mild incontinence' was 1.3–20 g of urine in 24 h, for 'moderate incontinence' was 21–74 g, and 'severe incontinence' was defined as ≥ 75 g (18). The KHQ was scored according to the developer's instruction and included the domains 'role limitation', 'physical limitation', 'social', 'personal/emotional', 'sleep/energy disturbance' and 'severity (coping) measures'.

The overall QoL was estimated by VAS on a scale of 0–10 from 'very good' (0) to 'terrible' (10).

As the Kolmogorov-Smirnov test indicated that the distribution of data deviated significantly from normality, we used non-parametric tests, i.e. the Mann-Whitney test for comparing two independent groups, and the Wilcoxon paired test for two related samples.

Results

The mean (range) age of patients was 54 (22–90) years. Five patients were unable to attend all sessions, but 69 (40 with urge incontinence and/or urgency/frequency, nine with stress incontinence, 10 with mixed incontinence and 10 with defecation problems) fulfilled the study endpoints. In all, 40 baseline and after-treatment bladder diaries, pad-tests, VAS scores, QoL and other evaluable data were completed satisfactorily. Evaluation of patients with defecation problems did not include a voiding diary, QoL, or a pad-test.

For the patients overall, there were no statistically significant differences between data before and after treatment for the voiding diary, pad-test, KHQ, VAS score, biofeedback registration or urodynamics. Furthermore, there were no significant improvements for any classified subgroup of patients, i.e. those with stress incontinence; urge incontinence; urgency/frequency; defecation problems; overactive pelvic floor (35 patients); those >50 years old, (35) or <50 years old (27); or those with previous treatments (35). Finally, the total patient group was stratified by the pre-treatment rest tone of the pelvic floor (>1–2 μV <, the basal amplitude registered on EMG). The only significant improvement was in the KHQ domain 'role limitations', which showed significant differences for all groups before and after treatment ($P < 0.05$).

Discussion

Few published studies have measured the effects of ExMI, and most focused on changes in urodynamic data and not on pelvic floor function as such. Several studies have shown the efficacy of pelvic floor muscle exercises, biofeedback training, functional electrical stimulation (19), percutaneous peripheral neuromodulation, sacral nerve stimulation and sacral modulation (19–21).

Yamanishi et al. (8) studied the urodynamic effects of functional continuous magnetic stimulation on urethral closure in normal volunteers. They concluded that functional continuous magnetic stimulation is safe, and found a significant increase in both the maximum intraurethral pressure during stimulation and in the maximum urethral closure pressure after stimulation.

Galloway et al. (9) developed pulsed magnetic technology for pelvic floor muscle strengthening in the treatment of urinary incontinence. In that study they found a significant reduction in the median number of pads, as well as in the frequency of leakage episodes and detrusor instability. The best results were achieved in patients who used at most three pads/day and had not had previous continence surgery.

In a randomized comparative study, Yokoyama et al. (22) investigated the effects of ExMI and functional electrical stimulation on urinary incontinence after retro pubic radical prostatectomy, and concluded that both ExMI and functional electrical stimulation can be recommended for patients who want a rapid improvement of urinary incontinence after surgery. They also investigated ExMI treatment for urge incontinence; the results were less clear, but in their opinion ExMI therapy offers a new option for both urge incontinence and stress urinary incontinence (23).

Unsal et al. (24) evaluated the efficacy of ExMI in stress and urge urinary incontinence and found ExMI to be a non-invasive, effective and painless treatment for stress and urge incontinence in women. Chandi et al. (1) evaluated the efficacy and applicability of functional magnetic stimulation of the pelvic floor for treating urinary incontinence in

women, stating that it is a safe, non-invasive and painless treatment for urinary incontinence, and is effective and easy to administer as an outpatient treatment. Few studies have focused on the impact of ExMI on pelvic floor function. Culligan et al. (25) studied its effect on pelvic muscle strength (measured by perineometry) in primiparous women, but found no difference between women receiving active or sham ExMI treatments in the early postpartum period.

In the present study we found no significant improvement in urodynamics, pelvic floor muscle strength, pad-test, voiding diary or VAS scores. There was a significant improvement only in the 'role limitations' domain of the KHQ.

We noted that in some of the present patients the rest tone of the pelvic floor (the basal amplitude registered on EMG) was higher after treatment than before. This might be a side-effect of stimulation of the efferents and/or afferents of the pudendal nerve. The question remains as to whether the present results were flawed by this motor effect of ExMI.

Some authors state that ExMI strengthens the pelvic floor muscles, but that the mode of action of electrical stimulation remains unclear. There is still little known about how to administer pelvic floor treatment most effectively. Fall et al. (26) investigated electrode positioning and the electrical variables used for stimulation. For electrical stimulation to be effective, the intensity must be sufficient to elicit impulses in a relevant nerve. The threshold intensity varies with the nerve fibre diameter, the distance between the nerve and the stimulating electrode, and the pulse configuration, so an optimum response requires a specific probe design. From the present findings, we conclude that the probes presently used for electrostimulation and biofeedback training to treat pelvic floor dysfunction is not optimal for the structures that we want to stimulate or to register (27).

Concerning the significant improvement in the domain of 'role limitations' of the KHQ, Kelleher et al. (17) designed and validated a condition-specific QoL questionnaire for assessing women with urinary incontinence, and used it to assess women with specific urodynamic diagnoses. Reese et al. (18) used country-specific psychometric analysis of health-related QoL, concluding that psychometric testing supports the reliability and

validity of the KHQ. The findings for QoL in these groups of patients are inconsistent; there is a discrepancy between the degree of negative feelings as reported by the patients and those we think they are actually experiencing (28, 29). This phenomenon of under-reporting (the 'response shift') is most common in self-reported measures. The response shift refers to a change in a respondent's evaluation of a target construct as a result of: (i) a change in the respondent's internal standards of measurements, (ii) a change in the respondent's values, or (iii) a redefinition of the target construct. An effective clinician-patient communication might 'teach' response shifts, by training people to change their internal standard values or the conceptualization of QoL (Table 1).

Table 1 The KHQ domains

Domain	**Cronbach's α**	**Mean (SD)**	**P**
Role limitations	0.8029	0.59 (1.60)	0.04
Physical limitations	0.8384	0.13 (1.68)	0.68
Social	0.7707	0.17 (1.43)	0.51
Personal	0.8422	0.23 (1.59)	0.70
Emotional	0.6451	−0.031 (1.71)	0.95
Sleep/energy disturbance	0.7522	0.29 (0.94)	0.20
Severity (coping) measures	0.7695	0.40 (2.75)	0.42
Symptom severity*	NA	NA	NA

** Symptom severity is a symptom checklist weighted by severity, thus Cronbach's α was not calculated. Incontinence impact and general health perception are one-item domains and are thus excluded from this table.*

This response shift might be responsible for the improvement of the domain 'role limitations' in the present study.

In conclusion, there were no differences in pelvic floor muscle activity, pad-test, QoL, voiding diary and urodynamics in patients treated with ExMI. ExMI appeared to have no

beneficial effect on pelvic floor function in the present patients, and in some, we even noticed an adverse effect. The selected patient population may pose a limitation to the findings of the present study. In our opinion, 'the chair' is suitable to train awareness of the location of the pelvic floor, but the need for active pelvic floor muscle exercises remains.

The varying outcomes of several studies show that we need more tools to evaluate the effect and the mode of action of electrostimulation. There is also a lack of knowledge of the way to administer pelvic floor treatment most effectively. We need more information about the efficacy of the pad-test, voiding diary and a standardization of registering pelvic floor muscle activity. In short, we need more randomized studies.

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Chapter 7

Simultaneous Sacral and Tibial Transcutaneous Electrical Nerve Stimulation: urodynamic evaluation

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Introduction

Electrostimulation is thought to modulate the neural behaviour of the bladder and is applied for example in patients with symptoms of Over Active Bladder (OAB) syndrome (1). Intravaginal stimulation, percutaneous tibial nerve stimulation, and sacral neurostimulation all have been reported to modify detrusor function (2-4). Neurostimulation using Transcutaneous Electrical Nerve Stimulation (TENS) has been advocated for the treatment of detrusor over activity, stress incontinence and interstitial cystitis(IC) (5). The mode of action of TENS was initially thought to be due to altered sensation or to completion with or masking of pain (6, 7).

Because clinical results were promising, studies assessed various aspects of this therapy. Compared to placebo, there are conflicting publications reporting no significant changes in urodynamics versus significant changes in first desire to void, maximum cystometric capacity and threshold volume in the suprapubic TENS group . TENS over the S2 - S4 dermatome has been studied using both clinical and urodynamic parameters, showing that it might improve urodynamical parameters. S2- S4 TENS has been solely compared to no TENS, sham TENS, suprapubic TENS and tibial nerve TENS solely. PTNS has been introduced for the treatment of lower urinary tract dysfunction. The precise mode of action of electrostimulation is unclear, but in literature is believed “to restore the balance within the central nervous system” (11-13).

The International Continence Society (ICS) has defined overactive bladder (OAB) syndrome, as urgency with or without urge incontinence, usually with frequency and nocturia, in the absence of proven infection or obvious pathology. and recognized OAB as a significant symptom complex syndrome affecting millions of people worldwide. In our center we have a very specific patient population. Most patients were refractory to conventional therapy, such as, pelvic floor muscle exercises, biofeedback training, intravaginal electrostimulation, PTNS and Sacral Nerve Stimulation (SNS) as well. In literature the effect of neurostimulation at the level of the n. tibialis (invasive: PTNS) and direct stimulation on the dorsal sacrum (neuromodulation or TENS: S2-S3) have been described. The effect of the procedure has been attributed to stimulation of the afferents

to the bladder. Both procedures have been used at our institution with varying success. Some patients appeared to be refractory to either procedure. In order to increase the success rate we have tried if the combination of both procedures would increase yield of the stimulation.

We decided to combine TENS on the tibial nerve and TENS applied at the S2-S4 foramina. We performed this study to quantify the acute effect of one single application of TENS in patients with symptoms of the overactive bladder syndrome using urodynamic parameters.

Materials and Methods

Forty consecutive female patients diagnosed with urgency/frequency and/or urge incontinence, but without stress incontinence and/or combined incontinence were included in a prospective study. Before urodynamic measurements all patients underwent comprehensive evaluation, including patient history, physical examination, urinary system ultrasound and a voiding diary.

To investigate the effect of TENS on urodynamic parameters in patients with symptoms of the OAB syndrome, we used the UD-2000 (Medical Measurement Systems, Enschede, the Netherlands) and a four fold microtip catheter (Gaeltec®) with three urethral and one bladder sensor during urodynamic evaluation. Filling rate was 30 ml/ min and we stopped if patients had a strong desire to void. In all patients two urodynamic investigations were performed in succession. Urodynamics were performed according to ICS procedures.

Patients were submitted to urodynamics (group I, n=20) or urodynamics plus TENS (group II, n=20) based on the availability of the pelvic floor physiotherapist during the study period. If the pelvic floor physiotherapist was present both investigations were performed simultaneously as described, if not present, only urodynamics were performed and TENS has been performed during a separate outpatient appointment. The investigation was a diagnostic procedure and not a treatment. Urodynamics of both groups have been compared retrospectively. The investigation was a diagnostic procedure and not a treatment. Urodynamics of both groups have been compared retrospectively.

TENS was given during urodynamics during 20 minutes. All patients had two urodynamic evaluations. Patients were informed about the combined form of urodynamics and TENS.

Measurements were performed during filling cystometry with a filling rate, at 30 ml/ min. Stimulation parameters were set to a burst of 2 Hz with pulse duration of 200 μsec and a frequency of 20 HZ. Stimulation intensity was adjusted individually to a level just below that giving rise to unpleasant sensation. We used surface electrodes made of carbon conductive rubber of 5 x 6 cm each. One was placed over the sacrum at the S2-S4 foramina and one over the tibial nerve just above the medial malleolus on the same side. In order to establish a good electrical contact, electrodes were incorporated in a wet sponge. Urodynamics procedures were performed and assessed according to ICS procedures by an experienced clinician in our department and by a pelvic floor physiotherapist. At the end of the second bladder filling when the patient has a normal desire to void, electrostimulation was stopped and "permission to void" is usually given.
Printouts of the urodynamic evaluation with and without TENS were assessed by an urologist. The urologist was blinded to the treatment group. We documented maximal detrusor pressure at micturition (cm H2O), first sensation of bladder filling (ml), cystometric capacity (ml), urethral pressure (cm H2O) micturition volume (ml) and peak flow (ml/sec). Rectal pressure was measured with a rectal balloon as a representative of the abdominal pressure (table). Statistical analysis was performed using Wilcoxon and paired T-tests in SPSS 12.1. Significance was defined as $p < 0.05$.

Results

All patients had been treated before with pharmacotherapy (44.3%), surgery (56 %) including colposuspensus and urethral dilatation or self-catheterization or even SNS (3%). Pelvic floor physiotherapy such as biofeedback training and/or intravaginal electrostimulation was performed in all patients.
The mean age of patients in group I was 37 years (range 31-65). Nine patients were diagnosed with urgency/ frequency, ten patients with urgency/frequency and urge

incontinence and one patient with urge incontinence. In this group, there were no significant changes between urodynamic parameters of both urodynamic evaluations.

The mean age of patients in group II was of 36 years (range 30-65). Ten patients were diagnosed with urgency/ frequency, nine patients with urgency/ frequency and urge incontinence and one patient with urge incontinence .By comparing both urodynamic evaluations in group II; it appeared that the first sensation of bladder filling, cystometric capacity, micturition volume, urethral pressure and peak flow showed statistical significant improvement ($p < 0.05$) during TENS (table 1).

Prior to TENS no involuntary detrusor contractions during bladder filling were registered in this patient population. However, as an expression of detrusor overactivity, a decreased maximaum cystometric capacity was observed at which patients could no longer delay micturition. By comparing the cystometric capacity and the micturition volume, there seems to be a relevant post-void residual (PVR).However, this was due to the fact that some patients were unable to void completely or even to void at all during urodynamics, because they were asked to refrain from straining or inhibited due to the urodynamic setting. Ultrasonography of the bladder prior to urodynamic investigation showed no relevant PVR in the studied patient population. There were no significant differences between the first filling of the patients in group I and group II.

Table 1. Urodynamic parameters before and during TRANS (significant if $p < 0.05$).

	Group 1 (n=20) Without stimulation			Group II (n=20) With Stimulation		
Parameters	**First Filling (± SEM)**	**Second filling (± SEM)**	**p- value**	**Before First filling (± SEM)**	**During Second filling (± SEM)**	**p- value**
Intravesical pressure (cm H2O)	90,2 ± 10,9	89,1 ± 7,4	ns	63,0 ± 3,8	48,4 ± 2,9	0,01
Abdominal pressure (cm H2O)	62,9 ± 9,0	64,1 ± 6,2	ns	43,2 ± 2,8	33,3 ± 5,8	0,14
Detrusor pressure (cm H2O),during micturition	35,2 ± 7,8	36,7 ± 5,4	ns	37,2 ± 36,8	24,4 ± 24,4	0,26
First sensation of bladder filling (ml)	164,6 ± 31,6	170,5 ±29	ns	195,7 ± 32,2	310,1 ± 31,7	0,0001
Cystometric capacity (ml)	337,3 ± 40	340,3 ± 39	ns	367,9 ± 40,0	433,4 ± 35,6	0,01
Micturation volume (ml)	190,3 ± 30	190,5 ± 32	ns	197,6 ± 42,6	252,1 ± 42,3	0,04
Average urethral pressure (cm H2O)	169,1 ± 15,0	169,0 ± 12	ns	154,6 ± 11,4	127,3 ± 7,7	0,01
Peak flow (ml/s)	11,0 ± 2,0	11,5 ± 1,9	ns	13,2 ± 2,2	26,5 ±7,8	0,08

Discussion

An acute effect of one application of TENS applied simultaneously to the tibial nerve and to S2-S4 foramina on bladder function using urodynamic parameters was demonstrated in patients with the OAB syndrome. Whether the findings represent the clinical effect of TENS in patients with complaints of OAB symptoms, needs to be clarified.

It appeared to be possible to combine TENS applied simultaneously to the tibial nerve and to S2-S4 foramina and to detect sensitive urodynamic parameters as First Sensation of bladder Filling (FSF), bladder capacity, and peak flow.

We believe that TENS facilitates the voiding process by lowering the urethral pressure. In this population with symptoms of the OAB syndrome, a high concurrence of overactivity of the resttone of the pelvic floor was found. Because the urethral sphincter is an integral part of the pelvic floor, we believe the urethral pressure is high, as a result of this phenomenon. No reference of this in the literature could be foundand this consistent phenomenon is the focus of a present study in our department

In the literature, sham TENS did not alter the outcome measures. A bias in this study may be that sham TENS was not performed. However, the relevance of sham TENS seems debatable, because patients are aware when no stimulation is given.

By comparing the cystometric capacity and the micturition volume, there seems to be a relevant PVR. However, this is due to the fact that some patients were unable to void completely or even to void at all during urodynamics, because they were asked to refrain from straining or inhibited due to the urodynamic setting (15). Ultrasonography of the bladder prior to urodynamic investigation showed no relevant PVR in the studied patient population studied.

With respect to the stimulation parameters for TENS, as yet there is no consensus regarding optimal stimulation parameters for percutaneous stimulation in patients with overactive bladder (16). As far as it is known, studies systematically evaluating the optimal settings of electrostimulation are lacking. Settings used in literature are mainly empirical. The most commonly used settings of TENS are a burst of 2 Hz with pulse duration of 200 μsec and a frequency of 20 HZ (Melzack and Wall). These settings were used for pain control by TENS. We used the same empirical parameters in OAB.

The mechanisms responsible for the beneficial effect of TENS in the treatment of bladder dysfunction remain unclear. One specific hypothesis is that detrusor over activity is known to be associated with female stress urinary incontinence as a result of pelvic floor relaxation. This may suggest that afferent nerve activity from the pelvic floor and urethra is involved in detrusor inhibition during bladder filling.

TENS applied only to the sacral dermatomes had a minimal effect on urodynamic data (17). Our experience supports this conclusion.

PTNS has a clear carry-over effect: 30 minutes of stimulation induces a lasting beneficial effect. Cat experiments, with a 5-minute stimulation of afferent nerves resulted in more

than 1 hour of bladder inhibition (18).SNS has been applied in various conditions refractory to conservative approaches. The success rates are usually in the range of 55-80% and are probably limited by the fact that no variables predictive of outcome have been identified. It is now generally accepted that SNS works via stimulation of the afferent rather than efferent nerves and effects at the level of the supraspinal nervous system (7, 19). Parallel to the gate control theory for pain, it may also be suggested that stimulation of large somatic fibers could modulate or inhibit the thinner afferent A-delta or C fibers, thus decreasing the perception of urgency.

In the experience of our institute, the treatment with TENS applied simultaneously to the tibial nerve and to S2-S4 foramina was effective.

Conclusion:

In the present study an acute effect of one application of TENS applied simultaneously to the tibial nerve and to S2-S4 foramina on bladder function using urodynamic parameters in patients with the OAB syndrome was demonstrated. Whether the findings represent the clinical effect of TENS in patients with complaints of OAB symptoms, needs to be clarified.

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Chapter 8

Acute effect of one single application of intravaginal electrostimulation on urodynamic parameters in patients with the overactive bladder syndrome

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Introduction

In 2002 the International Continence Society defined the overactive bladder (OAB) as urgency with or without incontinence, with frequency and nocturia in the absence of local pathological or hormonal factors, a symptom-based definition (1).

Patients with symptoms of the OAB-syndrome can be treated by medication (anticholinergics), biofeedback training, electrical stimulation and pelvic floor muscle exercises (PFM). During the past decades, electrical stimulation of the pelvic floor, bladder, sacral roots and pudendal nerves, has been reported to be an effective treatment option (2). There are different techniques of electrical stimulation, like intra-anal or vaginal stimulation, Tibial Nerve Stimulation (3) and Sacral Nerve Stimulation (4). Extra corporeal magnetic innervation therapy (ExMI) is a more recent technique (5; 6). According to previous studies, electrostimulation of the external urethral sphincter inhibits and depresses unstable bladder contractions and decreases the frequency of micturition (7; 8). The lack of controlled parameters has made it difficult to evaluate the true efficacy of intravaginal electro stimulation (ES). Moreover the stimulation equipment as well as the treatment regimens are not standardized and it is difficult to draw conclusions about electrical parameters of frequency, pulse duration, pulse - to- rest ratio, length of treatment, power and accurate success rates (9). Almost three decades ago, Erlandson and Fall et al, made a first attempt to standardize the technique. Erlandson referred not only to electrode position but also to the choice of electrical parameters used for stimulation (10). The precise mode of action of electrostimulation is unclear, but it is believed “to restore the balance within the central nervous system” (11).

Based on previous studies, induction of bladder inhibition is most effective when using a frequency of 5-10 Hz. (12).

We performed this study to quantify the acute effect of one single application of intravaginal ES in patients with symptoms of the overactive bladder syndrome using urodynamic parameters.

Material and methods

Forty consecutive female patients diagnosed with urgency/frequency and/or urge incontinence, without stress incontinence and/or combined incontinence were included in a prospective study. Before urodynamic evaluation all patients underwent comprehensive evaluation, including patient history, physical examination, urinary system ultrasound and a voiding diary.

To investigate effect of intra vaginal electrostimulation, we used the UD-2000 (Medical Measurement Systems, Enschede, the Netherlands). Urodynamics were performed with a four fold micro tip catheter (Gaeltec®) with three urethral and one bladder pressure measuring electrodes. Rectal pressure was measured with a rectal balloon as a representative of the abdominal pressure. Urodynamics were performed according to ICS recommendations. A fill rate of 30 ml/min was used. First sensation of Filling (FSF) and maximum cystometric capacity was measured. Subjects were the asked to void without straining. Voided volume and maximal urethral pressure were measured. In all patients two urodynamic investigations were performed in succession.

Patients were submitted to urodynamics only (group I, n=20) or urodynamics plus one application of intravaginal electrostimulation (group II, n=20) Patients were consecutively submitted to urodynamics or urodynamics plus electrostimulation based on the availability of the pelvic floor physiotherapist during the study period. If the pelvic floor physiotherapist was present both investigations were performed simultaneously as described, if not present, only urodynamics were performed during a separate outpatient appointment.

In group II, prior to the second urodynamic evaluation, electrostimulation was applied by a pelvic floor physiotherapist using the Myomed 932® (Enraf Nonius, Delft, the Netherlands) with a vaginal probe (EMG, 2 rings, V.M.P.Bioparc®*). The probe was inserted up to the thinnest part, at the level of the introitus. Stimulation parameters were set at a frequency of 8 Hz, pulse duration of 1000 μsec and no pulse to rest, during 20 minutes. Stimulation intensity was adjusted individually to a level just below a level giving unpleasant sensations. Urodynamic procedures were repeated after the 20 minutes of intravaginal stimulation by an experienced clinician in our department.

At the end of the second bladder filling when the patient has a normal desire to void, electrostimulation was stopped and "permission to void" is usually given.

Printouts of the urodynamic evaluation with and without intravaginal electrostimulation were assessed by an urologist. The urologist was blinded to the treatment group.

We documented maximal detrusor pressure at micturition (cm H2O), first sensation of bladder filling (ml), cystometric capacity (ml), urethral pressure (cm H2O) micturition volume (ml) and peak flow (ml/sec). Rectal pressure was measured with a rectal balloon as a representative of the abdominal pressure (table). Both policies are standard of care at our institute. The investigation was a diagnostic procedure and not a treatment. Urodynamics of both groups have been compared retrospectively.

Statistical analysis was performed using Wilcoxon and paired T-tests in SPSS 12.1. Significance was defined as $p < 0.05$.

Results

All except one patient had been treated before, with pharmacotherapy 41, 3 %, pelvic floor physiotherapy (all patients), urethral dilatation, and surgery (56 %), and including colposuspensus, urethral dilatation or even self-catheterization (3%).

The mean age of patients in group I was 37 years (range 31-65). Seven patients were diagnosed with urgency/frequency, ten patients with urgency/frequency and urge incontinence and three patients with urge incontinence. Observation during the urodynamic investigation indicated that the introduction of the probe had no influence on urodynamic parameters in both groups.

In this group, comparison of both urodynamic evaluations revealed no significant changes between urodynamic parameters.

The mean age of patients in group II was 45 years (range 22-67). Ten patients were diagnosed with urgency/frequency, one patient with urge incontinence and nine patients with urgency/frequency and urge incontinence.

Comparison of the initial urodynamic investigations of both groups revealed no differences. By comparing both urodynamic evaluations in group II, it appeared that the first sensation of bladder filling (FSF), cystometric capacity, micturition volume and peak flow showed statistical significant improvement ($p \leq 0.05$) during ES. Other urodynamic parameters improved but not statistically significant (Table).

	Group 1 (n=20) Without stimulation			Group II (n=20) With Stimulation		
Parameters	**First Filling (± SEM)**	**Second filling (± SEM)**	**p- value**	**First filling (± SEM)**	**Second filling during intravaginal ES (± SEM)**	**p- value**
First sensation of bladder filling (ml)	164,6 ± 31,6	170,5 ±29	ns	164,5 ± 31,6	321,0 ± 38,7	0,001
Cystometric capacity (ml)	317,3 ± 40	340,3 ± 39	ns	337,3 ± 40,0	491,4 ± 34,1	0,0001
Micturation volume (ml)	190,3 ± 30	190,5 ± 32	ns	197,6 ± 42,6	252,1 ± 42,3	0,05
Average urethral pressure (cm H2O)	154,1 ± 15,0	163,0 ± 12	ns	169,1 ± 16,5	160,2 ± 13,4	0,8
Peak flow (ml/s)	11,0 ± 2,0	11,5 ± 1,9	ns	11,0 ± 2,0	15,7 ± 2,3	0,008

Table: Comparison of urodynamic parameters of two urodynamic evaluations; group I, without ES and group II, with intravaginal ES during the second filling.

However, ultrasonography prior to urodynamic investigation indicated no relevant PVR in the studied patient population. There were no significant differences between patients in group I and group II.

Discussion

We were able to demonstrate an acute effect of one application of intravaginal ES on bladder function in patients with the overactive bladder syndrome using urodynamic parameters. Whether our findings represent the clinical effect of intravaginal electrostimulation in patients with complaints of OAB symptoms, needs to be clarified. We believe that intravaginal electrostimulation facilitates the voiding process by lowering the urethral pressure (Table). In this population with symptoms of the OAB syndrome we have found a very high concurrence of an overactivity of the rest tone of the pelvic floor. The urethral sphincter is an integral part of the pelvic

floor, so we believe the urethral pressure is high, as a result of this phenomenon. We could not find any reference of this in the literature and this (consistent) phenomenon is the focus of a present study in our department

Prior to intravaginal ES we registered no involuntary detrusor contractions during bladder filling in this patient population. However, as an expression of detrusor overactivity, we observed a decreased maximum cystometric capacity at which patients could not longer delay micturition. Ultrasonography of the bladder prior to urodynamic investigation indicated no relevant PVR in the studied patient population. The apparent post void residual (PVR) is due to the fact that some patients were unable to void completely or even to void at all during urodynamics, because they were asked to refrain from straining or due to the urodynamic setting (inhibition as described in literature)(13). With respect to the stimulation parameters for intravaginal electrostimulation, as yet there is no consensus regarding optimal stimulation parameters for intravaginal electrostimulation in patients with overactive bladder. As far as we know, studies systematically evaluating the optimal settings of electrostimulation are lacking. Settings used in literature are mainly empirical.

The mechanisms responsible for the beneficial effect of intravaginal electrostimulation in the treatment of bladder dysfunction remain unclear. One hypothesis is, that detrusor over activity is known to be associated with female stress urinary incontinence as a result of pelvic floor relaxation. This may suggest that afferent nerve activity from pelvic floor and urethra is involved in detrusor inhibition during bladder filling (14).

Percutaneous Tibial Nerve stimulation (PTNS has) a clear carry-over effect: 30 minutes of stimulation induces a lasting beneficial effect. Cat experiments in which a 5-minute stimulation of afferent nerves resulted in more than 1 hour of bladder inhibition; confirm the existence of this carry-over effect. Previous studies indicated a prolonged trial of up to three months was needed to determine whether ES could be considered potentially successful for a given subject. Success can be obtained in approximately two-thirds of patients, but the therapy has the disadvantage of the necessity of maintenance therapy (15). Groen et al stated that SNS has been applied in various conditions refractory to conservative approaches (16). The success rates are usually in the range of 55 % to 80 % and probably limited by the fact that no variables predictive of outcome have been identified. It is now generally accepted that SNS works via stimulation of the afferent rather than efferent nerves and effects at the level

of the supraspinal nervous system (17). Parallel to the gate control theory for pain, it may also be suggested that stimulation of large somatic fibers could modulate/inhibit the thinner afferent A-delta or C fibers, thus decreasing the perception of urgency (16; 18).

Pelvic floor physiotherapy is mostly based on experience and not evidence based. We indeed feel that in the absence of a gold standard all means should be used that give us something to hold onto. In the experience of our institute the treatment with intravaginal ES was effective.

The most accepted mode of action of intravaginal ES is related to its effect on the afferent nerves, innervating organs as the bladder, urethra, vagina, rectum and pelvic floor musculature (19). The effect of intravaginal ES on bladder, urethral and pelvic floor function depends on several factors: the distance to and configuration of the electrodes with respect to the appropriate nerve fibers, the excitability of these fibers, the transfer characteristics of the central pathways (in case of bladder inhibition) and the properties of the peripheral effector organ. Voorham et al. (20) stated that electrode placement has a profound influence on the threshold voltage: a small dislocation of the electrode carrier was often enough to cause a twofold or even threefold increase.

Literature is scarce on the topic of the optimal stimulation parameters. The generally accepted parameters are a frequency of 5-10 Hz and pulse duration of 400-1000 μ sec. In pelvic floor practice the pulse duration variates from 20 - 1000 μ sec, representing the limitations of equipment. In our institution we have experienced over the last 15 years that the combination of a frequency of 8 Hz, pulse duration of 1000 μsec and no pulse to rest proved to be optimal in relieving patient's symptoms. We are not aware of previous studies focused on intravaginal electrostimulation and urodynamics. Whether the acute effect of intravaginal electrostimulation we described in this study, represents its therapeutical effect as a result of 8-12 sessions is not proven yet. However the results underscore the rationale of intravaginal electrostimulation in patients with symptoms of the overactive bladder syndrome.

Conclusions.

In the present study we were able to demonstrate an acute effect of one application of intravaginal ES (8 Hz, pulse duration 1000 μseconds and no pulse to rest) on bladder

function using urodynamic parameters in patients with symptoms of the OAB. Whether our findings represent the clinical effect of intravaginal ES in patients with complaints of OAB symptoms, needs to be clarified.

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Chapter 9

Summary and General discussion

Chapter 1

Describes the history of pelvic floor disorders and pelvic floor physiotherapy, in the Netherlands as well as abroad. This thesis focuses on the treatment of pelvic floor dysfunction in patients with complaints of micturition, defecation and sexual function. Literature is scarce on the topic of pelvic floor investigation. Assessment of the function of the pelvic floor muscles is not easy, due to the lack of simple to use and reliable measurement techniques and the lack of cut-off values for pathological conditions. Furthermore the reproducibility of testing is questionable. Research on this topic is important, because many people suffer from the consequences of pelvic floor dysfunction such as loss of urinary control. Pelvic floor dysfunction affects social, psychological, domestic, occupational, physical and sexual life.
This thesis discusses the basic science and applications of pelvic floor dysfunction.

Chapter 2

During the diagnostic process a complete medical and injury history should be documented. A number of standardized questionnaires are available, for example the Pelvic Floor Distress Inventory (PFDI), the Pelvic Floor Impact Questionnaire (PFIQ), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) and the King's Health Questionnaire (KHQ). These questionnaires assess parts of pelvic floor dysfunction and/or quality of life, have been developed for specialists in Urology and Gynecology and are not focused on pelvic floor dysfunction in a broad sense related to micturition, defecation and/or sexual dysfunction. Only the recently published Electronic Pelvic Floor Assessment Questionnaire (e-PAQ) assesses all aspects of pelvic floor dysfunction.
Our department has developed a new administered questionnaire, the Pelvic Floor Inventories Leiden (PelFIs) for men and women in Dutch, in an attempt to create a new condition-specific pelvic floor questionnaire addressing all symptoms of micturition, defecation and sexual dysfunction related to pelvic floor dysfunction for use by professionals active in this field. We evaluated the validity and reliability of the PelFIs. The internal consistency of some of the scales was less than may be wished for, but we feel that from a clinical point of view, some questions cannot be removed from the questionnaire, despite these items resulting in a lower alpha. This

clinimetric view may seem at odds with our psychometric analysis, but these approaches have been shown to meet. We indeed feel that in the absence of a gold standard all means should be used that give us something to hold onto, and internal consistency can still be aimed for, with the goal of improving reliability. This should not be done by omitting clinically important items, but by adding additional items. The scales constipation and pelvic floor pain in men require attention in this sense, and items need to be added to bring alpha to a satisfactory level.

Chapter 3

Sexual abuse and sexual functioning are topics that health professionals find difficult to discuss. Women who present with pelvic-floor complaints often experience sexual difficulties; therefore, questions regarding sexual function should be a routine part of screening. Furthermore, pelvic-floor complaints are correlated with sexual abuse and asking about abuse should be a routine part of screening as well. Considering the fact that many practitioners have difficulty enquiring about abuse, we have suggested that a questionnaire may be helpful in improving the recognition and management of patients who have a history of sexual abuse.

Report of sexual abuse in a self-administered pelvic-floor questionnaire before visiting our outpatient pelvic-floor department was evaluated with the Pelvic Floor Leiden Inventories (PelFIs) administered by a pelvic- floor clinician in a later stage.

The percentage of sexual abuse detected by a taken questionnaire administered by a pelvic-floor clinician not confessed during a previous self-administered questionnaire.

Sexual abuse was reported in 20 patients with pelvic-floor dysfunction during administration of the PelFIs and was also evaluated on our pelvic-floor department. Only six of the patients (30%) did not note in the self-administered questionnaire that they had a history of sexual abuse.

A self-administered questionnaire for pelvic-floor complaints is reliable in detecting sexual abuse and can be helpful in daily practice.

Chapter 4

This study looked at pelvic floor dysfunction related to complaints of micturition, defecation and/or sexual dysfunction.
Diagnostic Investigation of Pelvic Floor Function (DIPFF) consists of a medical history, a physical examination, including the International Continence Society (ICS) Pelvic Organ Prolaps-Qualification (POP-Q) system in female patients and a biofeedback registration using a vaginal or anal probe. Based on our experience we defined an elevated rest tone as greater than 2 *µicro* Volt (*µ*V*)* using intravaginal or intra anal EMG.
A total of 238 patients with complaints of micturition, defecation and/ or sexual function were included in this study. Stratification of patients with a single complaint, a combination of two or three complaints of the micturition, defecation or sexual (all compartments of the pelvic floor) resulted in subgroups of respectively 30, 74 and 133 patients.
Electromyographic analysis revealed an elevated rest tone of the pelvic floor in 141 patients. In 184 patients we found involuntary relaxation of the pelvic floor.
Pelvic floor dysfunction is correlated with urinary, sexual or gastroenterological complaints. In our retrospective study we found that 77, 2 % of patients who presented to the clinic with urinary, gastrointestinal or sexual complaints had measurable pelvic floor dysfunction (69, 3 % overactive rest tone and 7, 9 % under active rest tone). In relation to the ICS terminology there is a need for a well defined normal versus elevated rest tone of the pelvic floor.

Chapter 5

Discusses the placement of probes in electro stimulation and biofeedback training in pelvic floor dysfunction. This investigation was performed in order to validate the anatomical positioning of commonly used and commercially available probes, positioned according to standard protocol as used in daily practice by pelvic floor physiotherapists. Based on our findings we conclude that the electrodes of the probes, as we use them now during electrostimulation and biofeedback training in the treatment of pelvic floor dysfunction, are not optimal for the structures we want to

stimulate or want to register. In our opinion, the anal and vaginal probes we presently use have a too large diameter, even in women after vaginal delivery.

Chapter 6

In a prospective study of the electromagnetic chair, 74 patients (65 women and 9 men) with urge incontinence, urgency/ frequency, stress incontinence, mixed incontinence and defecation problems were included. At baseline and after completing the study urodynamic evaluation, digital palpation electromyography (EMG) registration with a vaginal or anal probe (one week after the last treatment), were used to document pelvic floor function. A voiding diary, a pad-test, King's Health Questionnaire (KHQ) and a visual analogue scale (VAS) were completed at baseline and at the end of the study to evaluate voiding patterns and quality of life (QoL). There were no differences in pelvic floor muscle activity, pad-test, QoL, voiding diary and urodynamics in patients treated with ExMI. ExMI appeared to have no beneficial effect on pelvic floor function in the present patients, and in some patients, an adverse effect was noticed. The selected patient population may pose a limitation to the findings of the present study.

Chapter 7

We performed this study to quantify the acute effect of one single application of a combination of Transcutaneous Electrical Nerve Stimulation (TENS) on the tibial nerve and TENS applied to the sacrum at the S2-S4 foramina in patients with symptoms of the overactive bladder syndrome (OAB), using urodynamic parameters.
Prospectively forty female patients were consecutively selected by entry in two groups: urodynamics only and urodynamics combined with TENS. We applied TENS with a frequency of 20 Hz, a burst of 2 Hz and pulse duration of 200 μsec. Urodynamic evaluations were performed according to ICS standards.

By comparing urodynamic measurements in both groups, it appeared that the first sensation of bladder filling, cystometric capacity, micturition volume, urethral pressure and peak flow showed statistical significant improvement ($p < 0.05$) during TENS.

In the present study we were able to demonstrate an acute effect of one application of TENS in the combined setting on bladder function using urodynamic parameters in patients with the overactive bladder syndrome. Whether our findings represent the clinical effect of TENS in patients with complaints of OAB symptoms, needs to be clarified.

Chapter 8

Analogous to the study presented in Chapter 7 we performed this study to quantify the acute effect of one single application of intravaginal electrostimulation in patients with symptoms of the overactive bladder syndrome (OAB), using urodynamic parameters.

Prospectively forty female patients were consecutively selected by entry in two groups: urodynamics only and urodynamics combined with intra-vaginal Electrostimulation. We applied intravaginal electrostimulation with a frequency of 8 Hz, pulse duration of 1000 μsec and no pulse to rest. Urodynamic evaluations were performed according to ICS standards.

By comparing urodynamic measurements in both groups, it appeared that the first sensation of bladder filling, cystometric capacity, micturition volume, urethral pressure and peak flow showed statistical significant improvement ($p < 0.05$) during intravaginal electrostimulation.

In the present study we were able to demonstrate an acute effect of one application of intra vaginal electrostimulation on bladder function using urodynamic parameters in patients with the overactive bladder syndrome. Whether our findings represent the clinical effect of intravaginal electrostimulation in patients with complaints of OAB symptoms, needs to be clarified.

Concluding remarks

This thesis concludes that**:**

- The PelFIs is new practical and conceptually clear questionnaire that focus on micturition, defecation and/or sexual dysfunction, related to pelvic floor dysfunction. The use of PelFIs may provide a better and reliable insight in the patients' experience of specific complaints of pelvic floor dysfunction.
- In our opinion the interaction of a patient and clinician during the administration of a questionnaire is essential in order to gain the patients' trust and thus acquire a true perspective of FSDs and past or prevalent sexual abuse. We believe that a questionnaire administered by a clinician should be preferred to a self-administered questionnaire.
- Pelvic floor dysfunction is correlated with urinary, sexual or gastroenterological complaints. In our retrospective study we found that 77, 2 % of patients who presented to the clinic with urinary, gastro or sexual complaints had measurable pelvic floor dysfunction (69, 3 % overactive rest tone and 7, 9 % under active rest tone). In relation to the ICS terminology there is a need for a well defined normal versus elevated rest tone of the pelvic floor.
- The electrodes of the probes, as we use them now during electrostimulation and biofeedback training in the treatment of pelvic floor dysfunction, are not optimal for the structures we want to stimulate or to register.
- Extracorporeal Magnetic Innervation (ExMI) appeared to have no beneficial effect on pelvic floor function.
- We were able to demonstrate an acute effect of one application of TENS in the combined setting on bladder function using urodynamic parameters in patients with the overactive bladder syndrome
- We were able to demonstrate an acute effect of one application of intra-vaginal ES (8 Hz, pulse duration 1000 μseconds and no pulse to rest) on bladder function using urodynamic parameters in patients with symptoms of the OAB.

It has been established and it is my personal believe that pelvic floor physiotherapy has an important place in the treatment of micturition-, defecation problems and sexual dysfunction. Pelvic Floor Physiotherapy should be at least considered before irreversible surgery is advocated. The treatment is safe, minimal invasive and not costly. A consensus should be reached on treatment indications, patient selection and treatment protocol. Further research is necessary to determine the mechanisms of action, the efficacy and the proper placement of probes in the treatment of pelvic floor dysfunction.

This thesis is an effort towards evidenced based pelvic floor physiotherapy, but more fundamental research in pelvic floor science is necessary.

Chapter 10

Samenvatting en conclusies

Hoofdstuk 1

Geeft een overzicht van de geschiedenis van bekkenbodemdisfunctie en bekkenfysiotherapie, in Nederland en het buitenland. Dit proefschrift concentreert zich op de diagnostische behandeling van bekkenbodemdisfunctie bij patiënten met mictie- en defecatieklachten en klachten binnen het seksueel functioneren. De literatuur is beperkt op het gebied van onderzoek naar de bekkenbodem. Het meten van de functie van de bekkenbodemspieren is niet eenvoudig en eenduidig. Dit is mede het gevolg van het gebrek aan eenvoudige en betrouwbare meettechnieken en het ontbreken van grenswaarden met betrekking tot de pathologie. Verder blijkt het herhalen van testen onbetrouwbaar. Onderzoek op dit punt is belangrijk, omdat veel mensen lijden aan de gevolgen van bekkenbodemdisfunctie, zoals urineverlies. Bekkenbodemdisfunctie beïnvloedt het sociaal, psychisch, lichamelijk en seksueel functioneren en heeft invloed op het privéleven en werk.

Hoofdstuk 2

Gedurende het diagnostische proces moet een complete relevante medische voorgeschiedenis worden gedocumenteerd. Er bestaat een groot aantal gestandaardiseerde vragenlijsten, bijvoorbeeld de Pelvic Floor Distress Inventory (PFDI), de Pelvic Floor Impact Questionnaire (PFIQ), de Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) en de King's Health Questionnaire (KHQ). Deze beschrijven de bekkenbodemdisfunctie gedeeltelijk. Alleen de Electronic Pelvic Floor Assessment Questionnaire (e-PAQ) omvat het gehele bekkenbodem gebied. Deze vragenlijsten zijn ontwikkeld voor medisch specialisten, als urologen en gynaecologen en zijn niet bedoeld voor de dagelijkse praktijk van bekkenfysiotherapeuten. Binnen onze afdeling is de Pelvic Floor Inventories Leiden (PelFIs) voor vrouwen en mannen ontwikkeld met de opzet uniformiteit te verkrijgen door middel van een nieuwe, conditiespecifieke bekkenbodemvragenlijst. De lijst is bedoeld om een totaalbeeld te krijgen van de klachten van de patiënt, maar ook als onderzoeksinstrument.

Hoofdstuk 3

Seksueel misbruik en seksualiteit in het algemeen vinden artsen moeilijk om te bespreken. Vrouwen die zich melden met bekkenbodemklachten hebben vaak ook op seksueel gebied problemen, daarom zou de seksuele anamnese een standaardonderdeel van de analyse moeten zijn bij deze patiënten. Zorgvuldig vragen naar seksueel misbruik zou een vaste routine moeten zijn, aangezien bij patiënten met zo'n voorgeschiedenis frequent bekkenbodemklachten voorkomen. Omdat artsen het vaak moeilijk vinden naar seksueel misbruik te vragen, is de gedachte geopperd dat een vragenlijst mogelijk zou kunnen helpen bij het detecteren van seksueel misbruik. Het doel van de studie was de betrouwbaarheid in het detecteren van seksueel misbruik met behulp van een opgestuurde vragenlijst voordat de patiënt zich op onze polikliniek meldde.

Bevestiging van seksueel misbruik in een opgestuurde vragenlijst alvorens de patiënt het Bekkenbodemcentrum bezocht, werd vergeleken met de Pelvic Floor Leiden Inventories (PelFIs), een vragenlijst die later na verwijzing vanuit het Bekkenbodemcentrum door een bekkenfysiotherapeut werd afgenomen. Het percentage seksueel misbruik dat niet werd aangegeven in de eerste vragenlijst werd als uitkomstmaat genomen om de effectiviteit van de opgestuurde vragenlijst te bepalen.

Seksueel misbruik werd bevestigd door 20 patiënten met bekkenbodemklachten die werden geëvalueerd door een bekkenfysiotherapeut door middel van de PelFIs. Deze patiënten werden ook geëvalueerd op ons Bekkenbodemcentrum. Slechts 6 van de deze patiënten (30%) hadden niet aangegeven in de opgestuurde vragenlijst dat zij vroeger seksueel zijn misbruikt.

Een zelf in te vullen bekkenbodemvragenlijst voordat een patiënt zich meldt bij een polikliniek kan helpen in het detecteren van seksueel misbruik in de dagelijkse praktijk.

Hoofdstuk 4

Diagnostic Investigation of Pelvic Floor Function (DIPFF) bestaat uit een anamnese, lichamelijk onderzoek, inclusief het ICS Pelvic Organ Prolaps Quantification systeem

voor vrouwelijke patiënten en een biofeedbackregistratie met een intravaginale en/of intra-anale probe.

Totaal 238 patiënten met klachten betreffende mictie, defecatie en/of het seksueel functioneren werden geïncludeerd in deze studie: 97 mannen en 141 vrouwen met een gemiddelde leeftijd van 47 jaar (18-79). 94,1 % Van de patiënten had mictieklachten, 82,7 % van de patiënten had defecatieklachten en 64,7% van de patiënten had klachten ten aanzien van het seksueel functioneren. Onderverdeling van de patiënten na het afnemen van de PelFIs liet zien, dat slechts 12,6 % van de patiënten klachten had in één compartiment van de bekkenbodem, 31,3 % in twee compartimenten en 55,9 % in drie compartimenten (micti-, defecatie- en seksuele klachten).

Gebaseerd op onze omschreven definitie had 69,3% van de patiënten een verhoogde rusttonus van de bekkenbodem:81,5% van de mannen en 61,0 % van de vrouwen. 32 % Van de vrouwen had in de voorgeschiedenis seksueel misbruik en 14,4% van de mannen.

Hoofdstuk 5

In dit hoofdstuk wordt de elektrode plaatsing bij elektrostimulatie en biofeedbackregistratie bij bekkenbodemdisfuncties behandeld. Dit onderzoek is uitgevoerd om de anatomische positionering van de meest gebruikte en verkrijgbare intravaginale en intra-anale elektrodes in de dagelijkse praktijk van de bekkenfysiotherapeut te bepalen. Gebaseerd op onze bevindingen concluderen wij dat de elektroden van deze probes, die wij nu gebruiken bij de behandeling van bekkenbodemdisfuncties, niet optimaal zijn voor het stimuleren en/of registreren van de beoogde structuren. Zo hebben naar onze mening de anale en vaginale probes die wij nu gebruiken een te grote diameter, ook voor vrouwen na een bevalling.

Hoofdstuk 6

In deze pilotstudie evalueren wij de effecten van de behandeling met Extracorporeal Magnetic Innervation (ExMI) met het doel de klinische resultaten te correleren met de functionele veranderingen in de bekkenbodem.

In een prospectieve studie naar “de magnetische stoel”, zijn 74 patiënten (65 vrouwen en 9 mannen) met urgency/frequency, urge-incontinentie, stressincontinentie,

gemengde incontinentie en daefecatieproblemen geïncludeerd. Aan het begin en het eind van de studie ondergingen de patiënten een inwendig onderzoek, een urodynamisch onderzoek en een EMG-registratie met een vaginale of anale probe om de bekkenbodemfunctie te documenteren. Tevens werden een mictie dagboek, de Kings Health vragenlijst en een VAS- score ingevuld, om het mictiegedrag en de kwaliteit van leven te evalueren en kregen de patiënten een padtest. De behandeling bleek geen verschillen in bekkenbodemfunctie, padtest, mictiedagboek en urodynamisch onderzoek te geven. De door ons geselecteerde patiëntengroep kan wellicht een factor zijn bij de teleurstellende uitkomsten van deze studie.

Hoofdstuk 7

Onderzocht is in hoeverre het mogelijk is het directe effect te beoordelen van een eenmalige toepassing van Transcutaneous Electrical Nerve Stimulation (TENS) op de N.Tibialis en TENS op het sacrum ter hoogte van de foramina op S2-S4 niveau bij patiënten met symptomen van de overactieve blaas (OAB) tijdens urodynamisch onderzoek. Veertig vrouwelijke patiënten werden geïncludeerd in deze studie. Bij iedere patiënt werd tijdens het urodynamisch onderzoek de blaas twee keer gevuld. Voor de tweede vulling werd de functie van de bekkenbodem geregistreerd door middel van biofeedbackregistratie. Patiënten werden willekeurig ingedeeld in twee gelijke groepen. Bij groep I (N=20) werd alleen urodynamisch onderzoek uitgevoerd, in groep II werd het urodynamisch onderzoek gecombineerd met TENS. TENS werd toegepast gedurende de tweede blaasvulling.

TENS werd toegepast met een frequentie van 20 Hz, een burst van 2 Hz en een pulsduur van 200 µsec. Urodynamisch onderzoek werd toegepast volgens de richtlijn van het ICS.

Vergelijking van het urodynamische onderzoek van groep I en groep 2 liet een statisch significante verbetering zien ($p < 0.05$) in groep II waar TENS werd toegepast, in het eerste aandranggevoel, totale blaascapaciteit, mictievolume, urethrale druk en de piek flow.

In de huidige studie hebben wij kunnen aantonen, dat er een direct effect van TENS is op de functie van de blaas tijdens het urodynamisch onderzoek bij patiënten met symptomen van de overactieve blaas. De langere termijnresultaten van TENS zullen nog verder onderzocht moeten worden.

Hoofdstuk 8

Analoog aan het in hoofdstuk 7 beschreven onderzoek werd nu onderzocht in hoeverre het mogelijk is om de effecten van intravaginale elektrostimulatie te kwantificeren bij patiënten met klachten van urgency/frequency en /of urge-incontinentie (overactieve blaas) met behulp van urodynamisch onderzoek.
Veertig vrouwelijke patiënten werden geïncludeerd in deze studie. Bij iedere patiënt werd tijdens het urodynamisch onderzoek de blaas twee keer gevuld. Voor de tweede vulling werd de functie van de bekkenbodem geregistreerd door middel van biofeedbackregistratie.
Patiënten werden willekeurig ingedeeld in twee groepen. Bij groep I (N=20) werd alleen urodynamisch onderzoek uitgevoerd, in groep II werd het urodynamisch onderzoek gecombineerd met intravaginale elektrostimulatie. Deze elektrostimulatie werd toegepast gedurende de tweede blaasvulling. Tijdens elektrostimulatie werd een pulsduur van 1000µsec, een frequentie van 8 Hz en geen pauzeduur toegepast. Bij vergelijking van beide urodynamische onderzoeken bleek dat in groep II het eerste vullinggevoel, de totale blaascapaciteit, de intravesicale druk en de piekflow een statistisch significante verbetering gedurende elektrostimulatie gaf. Andere urodynamische parameters verbeterden, maar niet significant. Een verhoging van de rusttonus werd gezien bij 17 van de 20 patiënten.

Slot conclusies

Eigen onderzoek, beschreven in dit proefschrift levert de volgende conclusies op:

- De ontwikkeling van de Pelvic Floor Inventories Leiden (PelFIs) is een nieuwe en duidelijke vragenlijst, die zich richt op patienten met mictie, defecatieklachten en/of klachten binnen het seksueel functioneren gerelateerd aan bekkenbodemfunctiestoornissen . Het gebruik van de PelFIs zou kunnen voorzien in een beter inzicht in de klachten van patiënten met bekkenbodemdisfunctie.
- Naar onze mening is de communicatie tussen de specialist en de patiënt gedurende het afnemen van een vragenlijst essentieel ten einde het vertrouwen van de patiënt te verkrijgen en hiermee een duidelijk beeld te verwerven van

het seksueel functioneren van de patiënt en eventueel seksueel misbruik in de voorgeschiedenis.

- Een diagnostisch onderzoek van de bekkenbodemfunctie(DIPPF), is een essentieel diagnostisch instrument en als zodanig een voorwaarde voor een optimale behandeling.
- De plaatsing van de elektrodes van de probes, die wij nu gebruiken voor elektrostimulatie en biofeedbackregistratie, zijn niet optimaal voor de structuren die we willen stimuleren en/of registeren.
- "De magnetische stoel"(ExMI), blijkt in onze patiëntenpopulatie geen verbeteringen te geven in de functie van de bekkenbodem.
- Het bleek mogelijk de effecten van transcutane elektrostimulatie van de afferente takken van de N. Pudendus op de blaasfunctie met behulp van urodynamische parameters te kwalificeren. Deze bevindingen maken de weg vrij voor verbetering van de werking bij verlichting van klachten van de overactieve blaas bij patiënten die resistent zijn voor standaardbehandelingen.
- Ook eenmalige intravaginale elektrostimulatie (1000 μsec, 8 Hz en geen pauzeduur) liet een significante verbetering zien van de urodynamische parameters bij patiënten met klachten van het overactieve blaassyndroom.

Deze bevindingen bevestigen mijn overtuiging, dat bekkenfysiotherapie een belangrijke plaats heeft bij het behandelen van mictie- en defaecatieklachten en seksuele functiestoornissen. Bekkenfysiotherapie moet op zijn minst overwogen worden voordat operaties worden uitgevoerd.
De behandeling is veilig, minimaal invasief en niet kostbaar.
Er moet consensus komen over behandelindicaties, patiëntenselectie en behandel-protocollen. Verder onderzoek is noodzakelijk om het werkingsmechanisme van elektrostimulatie, de effectiviteit van de behandeling en elektrodeplaatsing binnen de bekkenfysiotherapeutische behandeling van bekkenbodemdisfunctie vast te stellen.
Dit proefschrift probeert een bijdrage te leveren aan een wetenschappelijke benadering van bekkenfysiotherapie, maar illustreert tevens dat meer basaal onderzoek noodzakelijk is.

Appendices

Anamneselijst vrouw
Anamneselijst man

Anamneselijst vrouw

Nummer: _____

1. Geboorte datum: …./…./….

2. Intake datum: …./…./….

3. Indicatie:

4. Wat zijn uw klachten? Specifieke omschrijving patiënt;

5. Oorzaak:
   a. partus
   b. aangeboren
   c. ongeluk/trauma
   d. urologische operatie
   e. chirurgische operatie
   f. gynaecologische operatie
   g. overgang
   h. onbekend

6. Duur van de klachten.
   a. minder dan een half jaar
   b. 6-12 maanden
   c. 1 tot 2 jaar
   d. langer dan 2 jaar

Domein algehele gezondheid

7. Hoe zou u uw algehele gezondheid willen omschrijven?
   a. uitstekend
   b. zeer goed
   c. goed
   d. matig
   e. slecht

8. a. lengte in cm:
   b. gewicht in kg:

9. Werkt u?
   a. fulltime
   b. parttime
   c. huisvrouw
   d. WAO, ZW
   e. student
   f. pensioen
   g. VUT
   h. WW

10. Welk werk doet u?

11. Hoe woont u?
    a. zelfstandig
    b. aanleunwoning
    c. verzorgingstehuis
    d. ouders
    e. begeleid wonen

12. Heeft u een partner?
    a. ja, mannelijk
    b. ja, vrouwelijk
    c. nee

13. Rookt u?
    a. ja
    b. nee

14. Zo ja hoeveel jaren rookt u?……
    a. Hoeveel sigaretten gemiddeld per dag?
    b. Hoeveel sigaren gemiddeld per dag?
    c. n.v.t.

15. Zo nee, heeft u gerookt?
    a. ja
    b. nee

16. Zo ja, wanneer bent u gestopt?…..
    a. Hoeveel sigaretten heeft u gemiddeld per dag gerookt?
    b. Hoeveel sigaren heeft u gemiddeld per dag gerookt?
    c. n.v.t.

17. Is het stoppen met roken van invloed geweest op uw klachten?
    a. ja
    b. nee
    c. n.v.t.

18. Zo ja, in welke zin?

19. Drinkt u alcohol?
    a. ja
    b. nee

20. Zo ja, hoeveel glazen gemiddeld per dag door de week?

21. Hoeveel glazen gemiddeld per weekend?

22. Hoeveel kopjes/bekers koffie drinkt u gemiddeld per dag?

23. Hoeveel glazen cola drinkt u gemiddeld per dag?

24. Bent u nog bij andere specialisten onder behandeling? ja nee
Zo ja, welke?
   a. cardioloog
   b. gynaecoloog
   c. endocrinoloog
   d. oncoloog
   e. algemeen internist
   f. chirurg
   g. uroloog
   h. longarts
   i. anders, nl:

25. Heeft u suikerziekte? ja nee

26. Komt dit in de familie voor? ja nee

27. Heeft u hartklachten? ja nee
   a. zo ja, wat voor?

28. Zijn er problemen met de bloedvaten? ja nee
   a. zo ja, wat voor?

29. Heeft u momenteel rugklachten? ja nee

30. Heeft u last van uw longen? ja nee

31. Heeft u een andere aandoening? ja nee
   a. zo ja, wat voor?

32. Gebruikt u medicijnen?
   a. ja, voor longen welke?
   b. ja, voor hart welke?
   c. ja, voor blaasklachten welke?
   d. ja, voor ontlasting welke?
   e. ja, antidepressiva welke?
   f. ja, pijnstilling welke?
   g. ja, anticonceptie welke?
   h. nee

33. Welke operaties heeft u tot op heden ondergaan?
   a. urologisch, nl:
   b. chirurgisch, nl:
   c. gynaecologisch, nl:
   d. geen

34. Eet u regelmatig?
   a. ja
   b. nee

35. Eet u vezelrijk?
    a. ja
    b. nee

36. Hoeveel vocht drinkt u gemiddeld per dag?
    a. minder dan 1 liter per dag
    b. 1 tot 1,5 liter per dag
    c. 1,5 tot 2 liter per dag
    d. meer dan 2 liter per dag

37. Bent u lichamelijk actief, zoals fietsen, wandelen, tuinieren, sporten?
    a. nooit
    b. ja, dagelijks een ½ uur of meer
    c. ja, 2 - 4 x per week
    d. ja, wekelijks
    e. onregelmatig

38. Bent u momenteel zwanger?
    a. ja
    b. nee
    c. n.v.t

39. Is er een kinderwens?
    a. ja
    b. nee
    c. n.v.t

40. Hoeveel zwangerschappen zijn er geweest?
    a. 1
    b. 2
    c. 3
    d. 4 of meer
    e. geen
    f. n.v.t.

41. Hoeveel bevallingen zonder keizersnede?

42. Hoeveel bevallingen met keizersnede?

43. Hoelang geleden?

44. Bent u bij de bevalling ingescheurd?
    a. ja, totaal
    b. ja, subtotaal
    c. nee
    d. onbekend
    e. n.v.t.

45. Bent u bij de bevalling ingeknipt?
    a. ja
    b. nee
    c. onbekend
    d. n.v.t.

46. Hoe zwaar waren de kinderen?
    a. kind 1 gram
    b. kind 2 gram
    c. kind 3 gram
    d. kind 4 gram
    e. kind 5 gram
    f. n.v.t.

47. Zijn er tijdens de bevalling hulpmiddelen toegepast?
    a. ja, vacuümverlossing
    b. ja, tangverlossing
    c. ingeleid i.v.m.:
    d. nee
    e. n.v.t

48. Hoe lang heeft u geperst tijdens de bevalling?
    a. 15 minuten
    b. 30 minuten
    c. 45 minuten
    d. 60 minuten
    e. meer dan 60 minuten
    f. n.v.t.

49. Menstrueert u nog?
    a. ja, regelmatig elke vier weken
    b. ja, maar onregelmatig
    c. nee, al een aantal maanden niet meer
    d. nee, al meer dan een jaar niet meer
    e. n.v.t.

50. Heeft u overgangsklachten?
    a. ja
    b. nee
    c. n.v.t.

<u>Domein verzakkingsgevoel</u>

51. Heeft u last van een vaginale verzakking?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd

52. Ziet u dit ook? Kunt u dit met de vingers voelen? Geeft dit last bij gemeenschap?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd

53. Bemerkt u vaginale zwelling bij ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd

54. Heeft u het gevoel dat er slijmvlies of ander weefsel uit de anus komt spontaan, bij lopen, bij ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd

Domein QoI

55. Hoe erg wordt u door uw verzakkkingsklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t.

56. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het verzakkingsgevoel **op dit moment** ervaart.

    Geen hinder Veel hinder
    I----------I
    10

Domein mictie verloop

57. Hoe vaak gaat u overdag gemiddeld naar het toilet om te plassen?
    a. 2 - 4 x per dag
    b. 5 - 7 x per dag
    c. 8 - 10 x per dag
    d. meer dan 10 x per dag

58. Hoe vaak gaat u 's-nachts gemiddeld naar het toilet om te plassen?
    a. nooit
    b. 1 - 2 x per nacht
    c. 3 - 4 x per nacht
    d. meer dan 4 x per nacht

59. Heeft u aandrang om te plassen?
    a. ja
    b. nee

60. Zo nee, wanneer plast u dan?

61. Hoe vaak heeft u aandrang om te plassen?
    a. continue
    b. ieder half uur
    c. ieder uur
    d. 2 - 4 uur
    e. langer

62. Heeft u meer aandrang

a. bij koude	ja	nee
b. als er een kraan loopt	ja	nee
c. bij nervositeit	ja	nee
d. onder de douche	ja	nee

63. Kunt u de plas uitstellen als u rustig zit?

a. direct rennen	ja	nee
b. paar minuten	ja	nee
c. goed onder controle	ja	nee
d. anders, nl:		

64. Kunt u de plas uitstellen als u bezig bent?

a. direct rennen	ja	nee
b. paar minuten	ja	nee
c. goed onder controle	ja	nee
d. anders, nl:		

65. Hoe plast u?
    a. zittend
    b. hangend boven het toilet
    c. thuis zittend, elders hangend boven het toilet.

66. Komt de plas?
    a. spontaan
    b. wachten
    c. wisselend
    d. anders, nl:

67. Komt de plas in een keer?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

68. Komt de plas in beetjes?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

69. Wilt u dat?
    a. ja
    b. nee
    c. n.v.t.

70. Moet u persen als u plast?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

71. Hoe is de straal gewoonlijk?
    a. meestal stevig
    b. meestal zwak
    c. meestal normaal
    d. anders, nl:

Domein QoL

72. Hoe erg wordt u door uw plasklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t.

73. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw plasklachten **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein verlies van urine

74. Verliest u wel eens urine?
    a. ja
    b. nee

75. Hoe vaak komt het verlies van urine voor?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

76. Hoeveel urine verliest u?
    a. druppels
    b. scheutje
    c. hele blaasinhoud
    d. anders, nl:
    e. n.v.t.

77. Verliest u overdag of 's-nachts urine?
    a. alleen overdag
    b. alleen 's-nachts
    c. dag en nacht
    d. n.v.t.

78. Wanneer komt het verlies van urine voor?
    a. bij hoesten, niezen, persen, lachen, wandelen, sporten ja nee
    b. bij opstaan uit stoel, traplopen ja nee
    c. bij bukken, tillen ja nee
    d. bij omdraaien in bed ja nee
    e. bij opstaan uit bed ja nee
    f. bij aandrang ja nee
    g. rond de menstruatie ja nee
    h. n.v.t.

79. Heeft u meer verlies:
    a. bij koude ja nee
    b. als er een kraan loopt ja nee
    c. bij nervositeit ja nee
    d. onder de douche ja nee
    e. n.v.t.

Domein QoL

80. Hoe erg wordt u door uw urineverlies beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders nl:
    g. n.v.t.

81. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het urineverlies **op dit moment** ervaart.

Geen hinder	Veel hinder
I----------I	
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Domein obstructieve mictie

82. Heeft u het gevoel dat de blaas na het plassen helemaal leeg is?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

83. Heeft u buikpijn in de blaasregio?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

84. Is het plassen zelf pijnlijk?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

85. Als u klaar bent met plassen en u staat op, druppelt u dan na?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

86. In hoeverre heeft u last van blaasontstekingen?
    a. nooit
    b. alleen vroeger
    c. minder dan 1 x per jaar
    d. 1 x per jaar
    e. 1 - 2 x per jaar
    f. meer dan 2 x per jaar

87. Is er wel eens bloed bij de urine?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

88. Gebruikt u opvangmateriaal voor de urine?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

89. Hoe vaak moet u het opvangmateriaal verschonen?
    a. 1 x per dag
    b. 2 x per dag
    c. 3 x per dag
    d. 4 x per dag
    e. meer dan 4 x per dag
    f. n.v.t.

90. Maakt u wel eens gebruik van een katheter?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. dagelijks

91. Heeft u als kind last gehad van bedplassen?
    a. nooit
    b. tot 10e jaar
    c. van 10e - tot 15e jaar
    d. ouder dan 15 jaar

Domein QoL

92. Hoe erg wordt u door uw plasklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders nl:
    g. n.v.t.

93. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het plassen **op dit moment** ervaart.

    Geen hinder Veel hinder
    I----------I
    0 10

Domein defeacatie verloop

94. Heeft u aandrang voor ontlasting als u naar het toilet gaat?
    a. ja
    b. nee
    c. soms

95. Zo nee, wanneer gaat u dan naar het toilet?
    a. bij aandrang
    b. vast tijdstip

96. Komt er dan altijd wat?
    a. ja
    b. nee
    c. soms

97. Hoe vaak heeft u gemiddeld per week overdag ontlasting?
    a. 1 x per 2 weken
    b. 1 x per week
    c. 3 - 4 x per week
    d. 1 - 2 x per dag
    e. meerdere keren per dag
    f. anders, nl:

98. Heeft u ‘s-nachts wel eens ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

99. Wat is de samenstelling van de ontlasting?
    a. dun, waterig
    b. brijïg
    c. zacht
    d. hard
    e. wisselend van samenstelling
    f. anders nl:

100. Voelt u de ontlasting naar buiten komen?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. tijdens iedere keer dat u naar de wc gaat
    f. anders nl:

101. Voelt u het verschil tussen een windje en ontlasting als dit komt?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

102. Heeft u helder rood bloedverlies tijdens de ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

Domein verlies van ontlasting

103. Verliest u wel eens ontlasting?
    a. ja
    b. nee

104. Zo ja, hoe vaak komt het verlies van ontlasting voor?
    a. minder dan 1 x per maand
    b. 1 x per maand
    c. 1 x per 2 weken
    d. minder dan 1 x per week
    e. 3 - 5 dagen per week
    f. altijd
    g. anders, nl:
    h. n.v.t.

105. Verliest u overdag of 's-nachts ontlasting?
   a. alleen overdag
   b. alleen 's-nachts
   c. dag en nacht
   d. n.v.t.

106. Kunt u de aandrang voor ontlasting 15 minuten ophouden?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

107. Wanneer komt verlies van ontlasting voor?
   a. bij hoesten, niezen, persen, lachen, wandelen, sporten ja nee
   b. bij opstaan uit stoel, traplopen ja nee
   c. bij bukken, tillen ja nee
   d. bij omdraaien in bed ja nee
   e. bij opstaan uit bed ja nee
   f. bij aandrang ja nee
   g. n.v.t.

108. Voelt u, dat u ontlasting verliest?
   a. ja
   b. nee
   c. soms
   d. n.v.t.

109. Verliest u wel eens zonder aandrang ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

110. Verliest u wel eens vocht uit de anus?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

111. Heeft u een geïrriteerde huid rond uw anus?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

112. Heeft u jeuk rond de anus?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

113. Kunt u windjes goed tegenhouden?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

114. Is er wel eens slijm bij de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

115. Gebruikt u opvangmateriaal voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

116. Hoe vaak moet u het opvang materiaal verschonen?
   a. 1 x per dag
   b. 2 x per dag
   c. 3 x per dag
   d. 4 x per dag
   e. meer dan 4 x per dag
   f. n.v.t.

117. Gebruikt u medicijnen voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

118. Houdt u rekening met uw voeding voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

Domein QoL

119. Hoe erg wordt u door verlies van ontlasting beperkt thuis, in uw werk, of vrijetijdsbesteding?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders nl:
   g. n.v.t.

120. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het verlies van ontlasting **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein obstipatie

121. Als u naar het toilet gaat voor ontlasting, heeft u dan meer dan 15 minuten nodig om uw ontlasting kwijt te raken?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

122. Heeft u het gevoel dat de darm helemaal leeg is na ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

123. Heeft u het gevoel dat de ontlasting in stukjes komt, meerdere keren achter elkaar?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

124. Moet u persen voor de ontlasting komt?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

Domein QoL

125. Hoe erg wordt u door uw verstoppingsklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders nl:
   g. n.v.t.

126. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw verstoppingsklachten **op dit moment** ervaart.

Geen hinder Veel hinder
|----------|
0 10

Domein bekkenbodempijn

127. Heeft u pijn rond de anus na ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders nl:

128. Heeft u buikpijn tijdens de ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

129. Heeft u kramp rond de anus?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

130. Heeft u pijn in het gebied tussen vagina en anus?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

131. Heeft u pijn aan het stuitje?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

132. Heeft u pijn bij de zitbeenknobbels?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

133. Heeft u pijn bij gemeenschap? ja nee nvt
   a. bij het binnenkomen ja nee nvt
   b. diep ja nee nvt

Domein QoL

134. Hoe erg wordt u door uw pijnklachten beperkt in thuis, in uw werk of vrijetijdsbesteding?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders nl:
   g. n.v.t.

135. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot de pijn **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein seksueel functioneren t.b.v. fysiotherapie

136. Heeft u
   a. wel gemeenschap
   b. geen gemeenschap

137. Geven eerder genoemde klachten problemen bij gemeenschap?
   a. ja
   b. nee
   c. anders nl:

138. Zo ja, welke?
   a. urine verlies tijdens gemeenschap ja nee
   b. urineverlies tijdens orgasme ja nee
   c. ontlastingverlies tijdens gemeenschap ja nee
   d. pijn bij binnenkomen ja nee
   e. pijn diep ja nee
   f. n.v.t.

139. Is er een relatie tussen het ontstaan van een blaasontsteking en gemeenschap? ja nee nvt

140. Heeft u nog zin om te vrijen? ja nee nvt

141. Komt dit door de klachten? ja nee nvt

142. Wilt u hulp hebben voor uw seksuologische klachten? ja nee nvt

Domein QoL

143. Hoe erg wordt u door uw klachten beperkt in uw seksueel functioneren?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders nl:
    g. n.v.t.

144. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot uw seksueel functioneren **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

145. Heeft u negatieve ervaringen in het verleden m.b.t. misbruik of mishandeling? ja nee

146. Zo ja, heeft u daarvoor hulp gehad? ja nee

147. Is dit verwerkt? ja nee

148. Zo nee, wilt u daarvoor hulp? ja nee

Anamneselijst man

Nummer: _____

1. Geboorte datum: …./…./….
2. Intake datum: …./…./….
3. Indicatie:
4. Wat zijn uw klachten? Specifieke omschrijving patiënt;

5. Oorzaak:
   a. TUR-P/open prostatectomie
   b. radicale prostatectomie
   c. aangeboren
   d. ongeluk/trauma
   e. urologische operatie
   f. chirurgische operatie
   g. ziekte
   h. onbekend

6. Duur van de klachten:
   a. minder dan een half jaar
   b. 6-12 maanden
   c. 1 tot 2 jaar
   d. langer dan 2 jaar

Domein algehele gezondheid

7. Hoe zou u uw algehele gezondheid willen omschrijven?
   a. uitstekend
   b. zeer goed
   c. goed
   d. matig
   e. slecht

8. a. lengte in cm:
   b. gewicht in kg:

9. Werkt u?
   a. fulltime
   b. parttime
   c. huisman
   d. WAO, ZW
   e. student
   f. pensioen
   g. VUT
   h. WW

10. Welk werk doet u?

11. Hoe woont u?
    a. zelfstandig
    b. aanleunwoning
    c. verzorgingstehuis
    d. ouders
    e. begeleid wonen

12. Heeft u een partner?
    a. ja, mannelijk
    b. ja, vrouwelijk
    c. nee

13. Rookt u?
    a. ja
    b. nee

14. Zo ja, hoeveel jaren rookt u?……
    a. Hoeveel sigaretten gemiddeld per dag?
    b. Hoeveel sigaren gemiddeld per dag?
    c. Hoeveel pijp gemiddeld per dag?
    d. n.v.t.

15. Zo nee, heeft u gerookt?
    a. ja
    b. nee

16. Zo ja, wanneer bent u gestopt?…..
    a. Hoeveel sigaretten heeft u gemiddeld per dag gerookt?
    b. Hoeveel sigaren heeft u gemiddeld per dag gerookt?
    c. Hoeveel pijp heeft u gemiddeld per dag gerookt?
    d. n.v.t.

17. Is het stoppen met roken van invloed geweest op uw klachten?
    a. ja
    b. nee
    c. n.v.t.

18. Zo ja, in welke zin?

19. Drinkt u alcohol?
    a. ja
    b. nee

20. Zo ja, hoeveel glazen gemiddeld per dag door de week?

21. Hoeveel glazen gemiddeld per weekend?

22. Hoeveel kopjes/bekers koffie drinkt u gemiddeld per dag?

23. Hoeveel glazen cola drinkt u gemiddeld per dag?

24. Bent u nog bij andere specialisten onder behandeling? ja nee
Zo ja, welke?
a. cardioloog
b. endocrinoloog
c. oncoloog
d. algemeen internist
e. chirurg
f. uroloog
g. longarts
h. anders nl:

25. Heeft u suikerziekte? ja nee

26. Komt dit in de familie voor? ja nee

27. Heeft u hartklachten? ja nee
a. zo ja, wat voor?

28. Zijn er problemen met de bloedvaten? ja nee
a. zo ja, wat voor?

29. Heeft u momenteel rugklachten? ja nee

30. Heeft u last van uw longen? ja nee

31. Heeft u een andere aandoening? ja nee
a. zo ja, wat voor?

32. Gebruikt u medicijnen?
a. ja, voor longen. Welke?
b. ja, voor hart. Welke?
c. ja, voor blaasklachten. Welke?
d. ja, voor ontlasting. Welke?
e. ja, antidepressiva. Welke?
f. ja, pijnstilling. Welke?
g. ja, erectiepillen. Welke?
h. anders, nl:
i. nee

33. Welke operaties heeft u tot op heden ondergaan?
a. urologisch, nl:
b. chirurgisch, nl:
c. geen

34. Bent u besneden?
a. ja
b. nee

35. Eet u regelmatig?
    a. ja
    b. nee

36. Eet u vezelrijk?
    a. ja
    b. nee

37. Hoeveel vocht drinkt u gemiddeld per dag?
    a. minder dan 1 liter per dag
    b. 1 tot 1,5 liter per dag
    c. 1,5 tot 2 liter per dag
    d. meer dan 2 liter per dag

38. Bent u lichamelijke actief, zoals fietsen, wandelen, tuinieren, sporten?
    a. nooit
    b. ja, dagelijks een ½ uur of meer
    c. ja, 2 - 4 x per week
    d. ja, wekelijks
    e. onregelmatig

Domein verzakkingsgevoel

39. Heeft u het gevoel dat er slijmvlies of ander weefsel uit de anus komt spontaan, bij lopen, bij ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd

Domein QoI

40. Hoe erg wordt u door uw verzakkingsgevoel beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t

41. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot uw verzakkingsgevoel **op dit moment** ervaart.

    Geen hinder Veel hinder
    I----------I
    0 10

Domein mictie verloop

42. Hoe vaak gaat u overdag gemiddeld naar het toilet om te plassen?
    a. 2 - 4 x per dag
    b. 5 - 7 x per dag
    c. 8 - 10 x per dag
    d. meer dan 10 x per dag

43. Hoe vaak gaat u 's-nachts gemiddeld naar het toilet om te plassen?
    a. nooit
    b. 1 - 2 x per nacht
    c. 3 - 4 x per nacht
    d. meer dan 4 x per nacht

44. Heeft u aandrang om te plassen?
    a. ja
    b. nee

45. Zo nee, wanneer plast u dan?

46. Hoe vaak heeft u aandrang om te plassen?
    a. continue
    b. ieder half uur
    c. ieder uur
    d. 2 - 4 uur
    e. langer

47. Heeft u meer aandrang:

a.	bij koude	ja	nee
b.	als er een kraan loopt	ja	nee
c.	bij nervositeit	ja	nee
d.	onder de douche	ja	nee

48. Kunt u de plas uitstellen als u rustig zit?

a.	direct rennen	ja	nee
b.	paar minuten	ja	nee
c.	goed onder controle	ja	nee
d.	anders, nl:		

49. Kunt u de plas uitstellen als u bezig bent?

a.	direct rennen	ja	nee
b.	paar minuten	ja	nee
c.	goed onder controle	ja	nee
d.	anders, nl:		

50. Hoe plast u?
    a. zittend
    b. staand
    c. thuis zittend, elders staand

51. Komt de plas?
    a. spontaan
    b. wachten
    c. wisselend
    d. anders, nl:

52. Komt de plas in een keer?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

53. Komt de plas in beetjes?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

54. Wilt u dat?
    a. ja
    b. nee
    c. n.v.t.

55. Moet u persen als u plast?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

56. Hoe is de straal gewoonlijk?
    a. meestal stevig
    b. meestal zwak
    c. meestal normaal
    d. anders, nl:

Domein QoI

57. Hoe erg wordt u door uw plasklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t.

58. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw plasklachten **op dit moment** ervaart.

Geen hinder	Veel hinder
I----------I	
0	10

Domein verlies van urine

59. Verliest u wel eens urine?
    a. ja
    b. nee

60. Hoe vaak komt het verlies van urine voor?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

61. Hoeveel urine verliest u?
    a. druppels
    b. scheutje
    c. hele blaasinhoud
    d. anders, nl:
    e. n.v.t.

62. Verliest u overdag of 's-nachts urine?
    a. alleen overdag
    b. alleen 's-nachts
    c. dag en nacht
    d. n.v.t.

63. Wanneer komt het verlies van urine voor?
    a. bij hoesten, niezen, persen, lachen, wandelen, sporten ja nee
    b. bij opstaan uit stoel, traplopen ja nee
    c. bij bukken, tillen ja nee
    d. bij omdraaien in bed ja nee
    e. bij opstaan uit bed ja nee
    f. bij aandrang ja nee
    g. n.v.t.

64. Heeft u meer verlies:
    a. bij koude ja nee
    b. als er een kraan loopt ja nee
    c. bij nervositeit ja nee
    d. onder de douche ja nee
    e. n.v.t.

Domein QoL

65. Hoe erg wordt u door het verlies van urine beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t.

66. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het urineverlies **op dit moment** ervaart.

    Geen hinder Veel hinder
    I----------I
    0 10

Domein obstructieve mictie

67. Heeft u het gevoel dat de blaas na het plassen helemaal leeg is?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

68. Heeft u buikpijn in de blaasregio?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

69. Is het plassen zelf pijnlijk?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

70. Als u klaar bent met plassen en u staat op, druppelt u dan na?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

71. In hoeverre heeft u last van blaasontstekingen?
    a. nooit
    b. alleen vroeger
    c. minder dan 1 x per jaar
    d. 1 x per jaar
    e. 1 - 2 x per jaar
    f. meer dan 2 x per jaar

72. Is er wel eens bloed bij de urine?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

73. Gebruikt u opvangmateriaal voor de urine?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

74. Hoe vaak moet u het opvangmateriaal verschonen?
    a. 1 x per dag
    b. 2 x per dag
    c. 3 x per dag
    d. 4 x per dag
    e. meer dan 4 x per dag
    f. n.v.t.

75. Maakt u wel eens gebruik van een katheter?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. dagelijks

76. Heeft u als kind last gehad van bedplassen?
    a. nooit
    b. tot 10e jaar
    c. van 10e - tot 15e jaar
    d. ouder dan 15 jaar

Domein QoL

77. Hoe erg wordt u door uw plasklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t

78. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het plassen **op dit moment** ervaart.

    Geen hinder Veel hinder
    I----------I
    0 10

Domein defeacatie verloop

79. Heeft u aandrang voor ontlasting als u naar het toilet gaat?
    a. ja
    b. nee
    c. soms

80. Zo nee, wanneer gaat u dan naar het toilet?
    a. bij aandrang
    b. vast tijdstip

81. Komt er dan altijd wat?
    a. ja
    b. nee
    c. soms

82. Hoe vaak heeft u gemiddeld per week overdag ontlasting?
    a. 1 x per 2 weken
    b. 1 x per week
    c. 3 - 4 x per week
    d. 1 - 2 x per dag
    e. meerdere keren per dag
    f. anders, nl:

83. Heeft u ‘s-nachts wel eens ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

84. Wat is de samenstelling van de ontlasting?
    a. dun, waterig
    b. brijïg
    c. zacht
    d. hard
    e. wisselend van samenstelling
    f. anders, nl:

85. Voelt u de ontlasting naar buiten komen?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. tijdens iedere keer dat u naar de wc gaat
    f. anders, nl:

86. Voelt u het verschil tussen een windje en ontlasting als dit komt?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

87. Heeft u helder rood bloedverlies tijdens de ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

Domein verlies van ontlasting

88. Verliest u wel eens ontlasting?
    a. ja
    b. nee

89. Zo ja, hoe vaak komt het verlies van ontlasting voor?
    a. minder dan 1 x per maand
    b. 1 x per maand
    c. 1 x per 2 weken
    d. minder dan 1 x per week
    e. 3 - 5 dagen per week
    f. altijd
    g. anders, nl:
    h. n.v.t.

90. Verliest u overdag of 's-nachts ontlasting?
    a. alleen overdag
    b. alleen 's-nachts
    c. dag en nacht
    d. n.v.t.

91. Kunt u de aandrang voor ontlasting 15 minuten ophouden?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

92. Wanneer komt verlies van ontlasting voor?

a. bij hoesten, niezen, persen, lachen, wandelen, sporten	ja	nee
b. bij opstaan uit stoel, traplopen	ja	nee
c. bij bukken, tillen	ja	nee
d. bij omdraaien in bed	ja	nee
e. bij opstaan uit bed	ja	nee
f. bij aandrang	ja	nee
g. n.v.t.		

93. Voelt u, dat u ontlasting verliest?
    a. ja
    b. nee
    c. soms
    d. n.v.t.

94. Verliest u wel eens zonder aandrang ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

95. Verliest u wel eens vocht uit de anus?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

96. Heeft u een geïrriteerde huid rond uw anus?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

97. Heeft u jeuk rond de anus?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

98. Kunt u windjes goed tegenhouden?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

99. Heeft u slijm bij de ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

100. Gebruikt u opvangmateriaal voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

101. Hoe vaak moet u het opvangmateriaal verschonen?
   a. 1 x per dag
   b. 2 x per dag
   c. 3 x per dag
   d. 4 x per dag
   e. meer dan 4 x per dag
   f. n.v.t.

102. Gebruikt u medicijnen voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

103. Houdt u rekening met uw voeding voor de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

Domein QoL

104. Hoe erg wordt u door verlies van ontlasting beperkt thuis, in uw werk of vrijetijdsbesteding?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:
   g. n.v.t.

105. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot het verlies van ontlasting **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein obstipatie

106. Als u naar het toilet gaat voor ontlasting, heeft u dan meer dan 15 minuten nodig om uw ontlasting kwijt te raken?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

107. Heeft u het gevoel dat de darm helemaal leeg is na de ontlasting?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

108. Heeft u het gevoel dat de ontlasting in stukjes komt, meerdere keren achter elkaar?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

109. Moet u persen voor de ontlasting komt?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:

Domein QoL

110. Hoe erg wordt u door uw verstoppingsklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
    a. nooit
    b. zelden
    c. soms
    d. regelmatig
    e. altijd
    f. anders, nl:
    g. n.v.t.

111. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw verstoppingsklachten **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein bekkenbodempijn

112. Heeft u pijn rond de anus na ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

113. Heeft u buikpijn tijdens de ontlasting?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

114. Heeft u kramp rond de anus?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

115. Heeft u pijn uitstralend in de testikels?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

116. Heeft u pijn na ejaculatie?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

117. Heeft u pijn aan het stuitje?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

118. Heeft u pijn bij de zitbeenknobbels?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:

Domein QoL

119. Hoe erg wordt u door uw pijnklachten beperkt thuis, in uw werk of vrijetijdsbesteding?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:
   g. n.v.t.

120. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot de pijn **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

Domein seksueel functioneren t.b.v. fysiotherapie

121. Heeft u
   a. wel gemeenschap
   b. geen gemeenschap

122. Geven eerder genoemde klachten problemen bij gemeenschap?
   a. ja
   b. nee
   c. anders, nl:

123. Zo ja, welke?

a. urine verlies tijdens gemeenschap	ja	nee
b. urineverlies tijdens orgasme	ja	nee
c. ontlastingverlies tijdens gemeenschap	ja	nee
d. pijn na ejaculatie	ja	nee
e. n.v.t.		

124. Heeft u nog zin om te vrijen? ja nee nvt

125. Komt dit door de klachten? ja nee nvt

126. Wilt u hulp voor uw seksuologische klachten? ja nee nvt

Domein erectiele disfunctie

127. Hoe sterk zou u het vertrouwen noemen, dat u erin had een erectie te kunnen krijgen en te behouden?
   - o heel sterk
   - o sterk
   - o middelmatig
   - o zwak
   - o heel zwak of helemaal afwezig

128. Hoe vaak is het de **afgelopen 4 weken** voorgekomen dat, terwijl u een erectie had door seksuele stimulatie, uw penis stijf genoeg was om te penetreren (binnen te gaan)?
   - o geen seksuele activiteit
   - o bijna nooit/nooit
   - o een paar keer (veel minder vaak dan de helft van de tijd)
   - o soms (ongeveer de helft van de tijd)
   - o meestal (veel vaker dan de helft van de tijd
   - o bijna altijd/altijd

129. Hoe vaak kon u de **afgelopen 4 weken** tijdens de geslachtsgemeenschap, uw erectie behouden nadat u bij uw partner was gepenetreerd (binnengegaan)?
   - o geen geslachtsgemeenschap geprobeerd
   - o bijna nooit/nooit
   - o een paar keer (veel minder vaak dan de helft van de tijd)
   - o soms (ongeveer de helft van de tijd)
   - o meestal (veel vaker dan de helft van de tijd)
   - o bijna altijd/altijd

130. Hoe moeilijk was het om de erectie te behouden tot het einde van de geslachtsgemeenschap?
   - o geen geslachtsgemeenschap geprobeerd
   - o heel erg moeilijk
   - o erg moeilijk
   - o moeilijk
   - o een beetje moeilijk
   - o niet moeilijk

131. Hoe vaak was het bevredigend voor u wanneer u probeerde geslachtsgemeenschap te hebben?
   - o niet geprobeerd
   - o bijna nooit of nooit
   - o een paar keer(veel minder dan de helft van de tijd)
   - o soms (ongeveer de helft van de tijd
   - o meestal (veel meer dan de helft van de tijd)
   - o bijna altijd of altijd

Domein QoL

132. Hoe erg wordt u door uw klachten beperkt in uw seksueel functioneren?
   a. nooit
   b. zelden
   c. soms
   d. regelmatig
   e. altijd
   f. anders, nl:
   g. n.v.t.

133. Wilt u hieronder, op een schaal van 0 tot 10, door middel van een kruisje aangeven hoe u uw klachten met betrekking tot uw seksueel functioneren **op dit moment** ervaart.

Geen hinder Veel hinder
I----------I
0 10

134. Heeft u negatieve ervaringen in het verleden m.b.t. misbruik of mishandeling? ja nee

135. Zo ja, heeft u daarvoor hulp gehad? ja nee

136. Is dit verwerkt? ja nee

137. Zo nee, wilt u daarvoor hulp? ja nee

Curriculum Vitae

The author of this thesis was born on the 17th of May 1955 in Delft, the Netherlands. She graduated in 1972 from the Hugo Grotius (HBS- A), Delft.

She intented to become a physical educator and started her training in 1972 at the 'Haagse Academie voor Lichamelijke Opvoeding', the Hague, the Netherlands.

In 1974 she decided to switch her study to physiotherapy at the the same institute and was certified in 1979.

From 1979 till 2000 she worked as a pelvic floor physiotherapist in a private practice. During this period she gave pregnancy education as well. In 1988 a major change in her career was induced by dr. J.B.V.M. Delemarre (1948-2005) who teached her invasive investigation in patients with pelvic floor dysfunction. In 1993 she obtained the certificate at the first pelvic floor course ever in the Netherlands (Deventer, the Netherlands).

From 1998 till 2000 she started working parttime at the department of Physiotherapy of the Leiden University Medical Center. From August 2000 until now she has been working fulltime at the Leiden University Medical Center and stopped her work in private practice. Since July 2004 she has been working at the department of Urology and started her doctoral research under the supervision of prof. dr. A.A.B. Lycklama à Nijeholt and dr. R.C.M.Pelger. In 2001 she obtained the Certificate "Modulaire Opleiding Bekkenfysiotherapie" (Breda, the Netherlands) and in November 2004 the certificate of the Erasmus Medical Center Rotterdam "Opleiding Bekkenfysiotherapie" containing the modules pregnancy education, peripartum pelvic pain and pelvic floor dysfunction. During the last few years she presented at national and international congresses (EAU, ICS, and AUA).

At the congress of the EAU 2006 she won a best poster session award.

Currently she is working as a pelvic floor physiotherapist/ scientist at the department of Urology of the Leiden University Medical Center. She is married to John and has two grown up children, Martijn and Jeroen.