PAULIINA AUKEE

Biofeedback training in stress urinary incontinence

Effect on muscle activity, the application of a home biofeedback device and the function of the pelvic floor musculature

Doctoral dissertation

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ABSTRACT
Pelvic floor muscles (PFM) play an essential role in the continence mechanism and therefore pelvic floor training (PFT) is widely used in incontinence therapy. Electromyography (EMG) serves as a method to investigate muscle performance. Due to their relative inaccessibility, PFM present a challenge for follow up of muscle function and training.

The present study was designed to evaluate the application of EMG-based home biofeedback training in stress urinary incontinence (SUI). The prototype of the hometraining device was tested with 11 female volunteers. The PFM activity of 66 women was measured with a new surface EMG device. In a randomized controlled pilot study, 65 urodynamically tested SUI women underwent intensive training with or without an EMG-based hometrainer during 1998-1999. Training lasted 12 weeks, and follow up was one year. In addition, 16 women were scanned with static and dynamic magnetic resonance images (MRI).

A strong correlation was found between the EMG values from consecutive measurements with all test probes. PFM activity values both in supine and standing positions were dependent on age (p = 0.004 and p = 0.009), but not on parity (p = 0.116 in supine, p = 0.365 in standing), episiotomies (p = 0.728, p = 0.905) or body mass index (p = 0.056, p = 0.302).

Primary results after 12 weeks of PFT were promising. There was a significant change over the time (p < 0.001) in the PFM activity values while standing in both groups. After one year the success rate, i.e., cured or improved and thus avoiding surgery, in the PFT group with home biofeedback was quite good, 68.8%. The EMG-based hometrainer is a valuable method in pelvic floor training, offering a possibility to follow exercises performed at home.

In the MRI study the thickness of the distal part of pubococcygeal muscle correlated significantly with EMG values during maximal contraction. Several variations in the levator ani muscle configuration were detected. The most obvious defects seen in the pubococcygeal muscles were asymmetry in thickness and loss of fibre continuity.

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Naisille, niin ihanille!
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Jyväskylä, October 2003

Pauliina Aukey
# Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BF</td>
<td>Biofeedback</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<td>EMG</td>
<td>Electromyography</td>
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<td>ES</td>
<td>Electrostimulation</td>
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<tr>
<td>HRT</td>
<td>Hormonal replacement therapy</td>
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<td>ISD</td>
<td>Intrinsic sphincter deficiency</td>
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<td>LA</td>
<td>Levator ani</td>
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<td>LPP</td>
<td>Leak point pressure</td>
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<td>MRI</td>
<td>Magnetic resonance imaging</td>
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<td>MUCP</td>
<td>Maximal urethral closure pressure</td>
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<td>MUP</td>
<td>Motor unit potential</td>
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<td>PCM</td>
<td>Pubococcygeal muscle</td>
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<td>PFM</td>
<td>Pelvic floor muscle</td>
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<td>PFT</td>
<td>Pelvic floor training</td>
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<td>OR</td>
<td>Odds ratio</td>
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<td>( r )</td>
<td>Correlation coefficient</td>
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<tr>
<td>SD (StD)</td>
<td>Standard deviation</td>
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<td>SUI</td>
<td>Stress urinary incontinence</td>
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<tr>
<td>TVT</td>
<td>Tension-free vaginal tape</td>
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<tr>
<td>( \mu \text{V} )</td>
<td>Microvolt</td>
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LIST OF ORIGINAL PUBLICATIONS

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1. **INTRODUCTION**

Stress urinary incontinence is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing (Abrams P et al. 2002). The prevalence of urinary incontinence is 16-28% among 20-60 year old women (Mäkinen et al. 1992a, Tuppurainen M et al. 1993, Møller et al. 2000, Samuelson et al. 2000a). SUI is the dominant type.

Pelvic floor training is defined as repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles (Abrams P et al. 2002). Before 2002 several expressions are used of PFT like PFM exercises. The aim of pelvic floor re-education is to increase the strength and functional activity of the pelvic floor muscles (Knight & Laycock 1994). These muscles play an essential role in the continence mechanism (Dyson 1995, Ulmsten 1997) and therefore in many cases may reduce the problem of stress incontinence. PFT is a widely used and well-established form of stress incontinence treatment with success rates varying from 21-84%, though with a better subjective than objective outcome (Burgio et al. 1986, Burns et al. 1993, Bø et al. 1999, Wilson et al. 1999).

The role of adjunctive biofeedback in PFT is controversial. Few studies have examined the impact of home BF devices on PFT. One study reported an improvement or cure rate of 85% after EMG-controlled home biofeedback training in stress and mixed incontinence (Hirsch 1999). In a randomised controlled trial that consisted of 16 office visits and home BF training, the objective cure rate after 6 months of training was 67% with a BF device in urodynamic SUI (Mørkved et al. 2002).

EMG has been used in sports, and occupational medicine, and rehabilitation to measure the activity of skeleton muscles as a determinant of muscle strength gain (Moritani & DeVries 1979, Väätäinen et al. 1995, Kankaanpää 1998). Modern technology has allowed the development of a selection of vaginal and rectal probes sensitive to pressure or EMG activity (Knight & Laycock 1994). Such devices may measure and collect the data of muscle exercises for later analysis, thus allowing perhaps fewer office visits. Also individual training programs with audio instructions are available in the most sophisticated versions (Mørkved et al. 2002).
In this study the applicability of an EMG based biofeedback device for both home and clinical use was tested. The ability of a new EMG device and software to measure PFM activity was tested with different types of electrodes. Because there has been evidence of muscle weakness among incontinent women, we measured the pattern of PFM activity both in incontinence women and controls. A randomized prospective pilot study of 35 incontinent women with a one-year follow-up was performed during 1998-1999. Both primary and follow-up results are presented in this thesis. Finally we carried out a static and functional magnetic resonance imaging (MRI) study to achieve a better understanding of pathophysiologic mechanisms behind SUI.
2. REVIEW OF THE LITERATURE

2.1. Some definitions of lower urinary tract disorders

The following definitions recommended by the International Continence Society (ICS) are used in the text (Abrams P et al. 2002):

SUI is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. The Finnish expression ‘ponnistusvirtsinkairu’ is optimal since it refers to physical and not to mental stress. Stress sign is the observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing.

The earlier term genuine SUI has been changed to urodynamic SUI, which is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction.

Urge urinary incontinence is the complaint of involuntary leakage accompanied by or immediately preceded by urgency. In mixed urinary incontinence, the involuntary leakage is associated with urgency and also with exertion, sneezing or coughing.

Pelvic organ prolapse can occur in association with urinary incontinence and other lower urinary tract dysfunction and may on occasion mask incontinence. Pelvic organ prolapse is defined as the descent of one or more of: the anterior wall, the posterior vaginal wall, and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. Absence of prolapse is defined as stage 0 support; prolapse can be staged from I to stage IV (Abrams P et al. 2002).

2.2. Epidemiological aspects of urinary incontinence

The self-reported incidence of urinary incontinence in women is 12-28% (Molander 1990, Mäkinen et al. 1992a, Tuppurainen et al. 1993, Möller et al. 2000, Samuelson et al. 2000a). There is tendency for the number of incontinent symptoms to increase with age (Molander 1990). A probable explanation of large variation in the reported prevalence of urinary incontinence is that different populations of women have been studied and different definitions of incontinence have been used.
SUI is the most frequent type of incontinence among young and middle aged women (Mäkinen et al. 1992a, Møller et al. 2000, Samuelson et al. 2000a). The prevalence of SUI is greatest before 50 years of age, whereas urge and mixed incontinence dominates in women over 50 years old (Mäkinen et al. 1992a, Simeonova et al. 1999, Møller et al. 2000). Female urinary incontinence seems to be a dynamic condition with a 5.9 % remission rate, a fact of which physicians should be aware when assessing and planning prevention and treatment strategies (Samuelsson et al. 2000b).

Urinary incontinence is a common phenomenon in all races and ethnic groups. Urodynamic studies have revealed some characteristic differences in incontinence mechanism between white and black nulliparous women (Howard et al. 2000). Hispanic, white, and Asian women have similar rates of urodynamic SUI. African American women have lower rates of urodynamic SUI than Hispanic and white women, but they have higher rates of detrusor instability (Duong et al. 2001).

2.2.1. Risk factors of urinary incontinence

Stress urinary incontinence is associated with aging, pregnancy, parity, childbirth, obesity, smoking, previous gynecological operations and weak PFM. Risk factors or causes for urinary incontinence need to be investigated in a prospective or longitudinal design in order to establish the temporal ordering between risk factors and onset of urinary incontinence (Hunskaar et al. 1999).

In cross-sectional studies a maximum in the prevalence of SUI reach the age of 50 to 55 years (Mäkinen et al. 1992, Simeonova et al. 1999, Møller et al. 2000). This finding is conflicting with muscular and hormonal changes occurring with aging. It is estimated that after the fifth decade of life the reduction of muscle strength is 10% per decade (Basu et al. 2002). Most women have also reached menopause, and urogenital aging occurs as a later manifestation of menopause. One explanation is a change in the physical environment (retirement age, decrease in physical activity) in postmenopausal women. The possibility of a cohort effect must be ruled out in a longitudinal study.

The self-reported prevalence of stress urinary symptoms three months postpartum is 24% (Wilson et al. 1996). PFT may protect against such symptoms. Maternal factors
influencing incontinence symptoms are an increased body mass index and multiparity. Women with infants weighing $\geq 4000\text{g}$ are at a higher risk of having such problems (Wilson et al. 1996, Højberg et al. 1999). The prevalence of self-reported morbidity after cesarean births is generally similar to that reported after unassisted vaginal births, with the exception of urinary incontinence, hemorrhoids, sexual problems and perineal pain, for which the rates were lower (Brown & Lumley, 1998). The protective value of cesarean section on incontinence symptoms is controversial and should be analysed in longitudinal studies that exclude other confounding factors.

In a 5-year longitudinal cohort study the prevalence of stress and urge incontinence five years after the first delivery were 30% and 15%, whereas the 5-year incidences were 19% and 11%, respectively (Vikstrup 2002). Obstetric risk factors for long-lasting SUI were vacuum extraction and episiotomy, but subsequent delivery seemed to be less important. Based on a prospective evaluation of pelvic floor innervation before and after a vaginal delivery, Snooks et al. (1990) proposed that pudendal nerve damage with partial reinnervation of the external anal sphincter muscle persists and may become more marked five years after vaginal delivery. This abnormality is associated with the development of SUI and faecal incontinence.

Nulliparity does not protect women from SUI later in life. The prevalence of self-reported SUI symptoms among nulliparous postmenopausal nuns is 30% (Buchsbaum et al. 2002). The same study (n = 149) found that the risk factors for those were body mass index (BMI), OR 1.15; hysterectomy, OR 2.17; depression, OR 2.96; and multiple urinary tract infections, OR 3.37.

Heavy exercise may induce incontinence (Nygaard et al. 1994, Eliasson et al. 2002). Activities most likely to provoke incontinence include jumping, high-impact landings, and running. Trampolinitists reported that urinary leakage started after a mean of 2.5 years of training. Leakage occurred during training without symptoms during daily life (Eliasson et al. 2002). Urinary incontinence among physically fit nulliparous women is presumed to be promoted by intrinsic sphincter deficiency (ISD) and not urethral hypermobility (Bø et al. 1994a).

There is a strong statistical relationship between current and former cigarette smoking and both stress and motor urge urinary incontinence in women (Bump &
McClish 1992). The increased risk for incontinence among smokers is not due to differences in age, parity, weight, or hypoestrogenic status.

Overweight is an independent risk factor for urinary incontinence and is associated with severe SUI symptoms (Kuh et al. 1999, Buchsbaum et al. 2002). Weight loss may resolve SUI (Bump et al. 1992).

Because collagen is responsible for the strength of supportive structures, several authors have studied the association between pelvic floor disorders including incontinence and abnormalities of collagen composition (Falconer 1998a). The possibility of genetic background of the abnormalities of collagen metabolism has inspired investigators to evaluate the family history of incontinence patients. The likelihood of a family history of incontinence is 2.6 to 9.6 times higher among incontinent than among continent women (Elia et al. 2002).

2.2.2. Urinary incontinence and the impact on quality of life

Incontinence is not a life-treating condition. Thus incontinence health care mainly focuses on better quality of life. To an individual person urinary incontinence causes hygienic problems and social embarrassment. Urinary incontinence may prevent from meeting people and prevent from participating in social events, exercise and sports activities. This may expose to isolation and weight gain problems. Women with SUI have reported lower quality of life than continent women, but better than urge and mixed incontinence women (Simeonova et al. 1999). However, only 6-16% of the interviewed women reported that they had sought medical attention for urinary incontinence (Mäkinen et al. 1992a, Simeonova et al. 1999). One possible explanation for that is that our primary health care system is not provided by enough resources, time and knowledge of the new treatment modalities of SUI.

Pubertal nerve injury or direct muscle damage may cause both anal and urinary incontinence as a result of combined pelvic floor dysfunction. The prevalence of anal incontinence among urodynamically proven SUI and urge with or without genital prolapse patients is 20%. (Meschia et al. 2002)
Patients with urge and mixed urinary incontinence are significantly more likely to have coexistent psychiatric illness than SUI patients (Melville et al. 2002). Similarly after adjusting for medical morbidity, functional status, and demographic variables, women with severe and mild-to-moderate incontinence were more likely to have depression than continent women (Nygaard et al. 2003). Depression-related stress or urge incontinence is idiopathic, and is not due to neuropathology or obstruction (Zorn et al. 1999). A possible explanation is altered serotonin function in the central neural control of lower urinary tract function (Zorn et al. 1999, Steers & Lee 2001, Norton et al. 2002).

SUI may have an impact on sexual matters. Every fourth incontinent patient has experienced incontinence during sexual activity (Hilton 1988, Gordon et al. 1999). Physicians should therefore discuss sexual matters with incontinent patients.

2.3. Anatomy of pelvic floor muscles (PFM)

2.3.1. PFM and their relation to other structures

According to anatomical concepts the pelvic floor is the pelvic diaphragm. It has two muscular components, coccygeus and levator ani (LA) muscles, which form support to pelvic viscera (Klutke & Siegel 1995). The levator ani has different components: the iliococcygeus, pubococcygeus and puborectalis muscles. The pubococcygeus muscle (PCM) is a thick structure that originates bilaterally from the pubic rami (Strohbehn et al. 1996, Shafik 1999). The muscle curves posteriorly and inferiorly past the urethra, vagina, and anorectum to form a sling as it joins its opposite half behind rectum (Strohbehn et al. 1996). This supportive sling around vagina and urethra is also called the levator sling (Figure 1). The PCM and its overlying endopelvic fascia and fascial condensations attach to the bladder, urethra, vagina, uterus and rectum (Critchley et al. 1980, Klutke & Siegel 1995). These portions are referred to by some investigators as the pubovaginalis, pubourethralis, puboanalis and puborectalis muscles, respectively (Strohbehn et al. 1996).
The second portion of LA, the iliococcygeus muscle, is a thin, flat muscle with anterior attachments to the pubic bone, lateral attachments to the arcus tendineus of LA and ischial spine and posterior attachments to anococcygeal raphe and coccyx (Strohbehn et al. 1996, Shafik 1999). The classic description of the downward convexity of the pelvic floor is based on cadaver studies (Dyson 1995). Muscular tone and vascular flow alter the anatomy in living erect women compared with cadaver studies. With the aid of MRI, recent studies have found that in living individuals the LA is shortened, elevated in position, and has a cranial and medial convexity (Constantinou et al. 2002).

Figure 1. Transversal section of the normal anatomy of the lower levator ani level. SP, symphysis pubis, U, urethra, V, vagina, LA (PCM), the pubococcygeal part of levator ani muscle i.e. levator sling.
2.3.2. Histology of PFM

Histomorphologically, the LA consists of type I (slow twitch type) and type II (fast twitch) fibers. Levator ani has a higher proportion of slow fibers (66%) than found in other human female muscle (48%) (Helt et al. 1996) which indicates that the LA is ideally suited to maintain tone over long periods of time (Critchley et al. 1980). The perianal levator ani is structurally in direct continuity with the external anal sphincter and they both have more type II fibers than the anterior part of levator ani (Critchley et al. 1980). In contrast, the external urethral sphincter consists of a single population of type I (slow twitch) fibers which indicates that those fibers maintain basal tone in the urethra (Gosling et al.1981). From a functional point of view, these findings mean that rapid movements of the LA assists in urethral closure. Since there is a heterogenous population of fibers in different parts of the LA muscle (Gilpin et al.1989), EMG activity should be recorded from different places of the LA, and different types of exercises should be performed in PFT.

2.3.3 Innervation of PFM

Innervation of the pelvic floor muscles is derived from the ventral roots of the second, third and fourth sacral nerve roots via the pudendal nerve. In addition, direct innervation to the cranial surface of the levator ani muscle from the S2, S3, S4 and S5 sacral roots has been described (Boirakhanavanat et al. 1997, Barber et al. 2002). The pudendal nerve leaves the pelvis by passing backwards between the piriformis and coccygeus muscles to enter the gluteal region through the lower part of the greater sciatic foramen (Le Gros Clark 1976). After a short course in the gluteal region the nerve passes through the lesser sciatic foramen medial to the internal pudendal artery to lie in the pudendal canal. This duplication of the fascia obturatoria in the lateral wall of the fossa ischiorectalis is also called Alcoks canal. Immediately after entering pudendal canal the nerve divides. The inferior rectal nerve extends a motor branch to the levator ani muscle and the cutaneous perianal and scrotal branches. The nerve terminates in the external anal sphincter at the 3 and 9 o’clock positions (Shafik & Doss 1999). Levator
muscles are supplied also by perineal nerve. The pudendal nerve sends branches to the perineal skin, penis or clitoris and the lower part of buttock. Figure 2.

Complete lower motor neuron lesions causes fibrillation of muscles without a nerve supply. After three weeks it can be measured as denervation activity. Partial lower motor neuron lesions (neurapraxia) lead to a decrease in the number of motor units (Cardozo 1997). In 1990 Allen et al. found evidence of damage after delivery in the innervation of the PCM. They tested 75 nulliparous at gestation week 36 and 2 months after delivery with needle-EMG. Denervation was detected in the 80 % of cases. Fortunately it seems that pudendal nerve damage during delivery is a reversible event (Snooks et al. 1990). Iatrogenic pudendal nerve injuries may occur in radical colorectal or gynecological surgery (Hollabau et al. 2000).

Figure 2. Schematic representation of the distribution of the pudendal nerve. EAS, external anal sphincter, V, vagina, U, urethra, LA, levator ani muscle.
2.4. The role of pelvic floor in the continence mechanism

The pelvic floor musculature plays as important role, especially in the female, by providing an additional occlusive force on the urethral wall (Dyson 1995). In addition, the muscle provides support for the pelvic viscera. The levator ani is connected to the urethra in bladder neck (DeLancey 1988, Shafik 1999). The muscle fibers of the most medial portion of the levator ani and smooth muscle collagen and elastin fibers of the vaginal wall and paraurethral tissues are connected to each other in the region of proximal urethra (DeLancey & Starr 1990, Ball et al. 1997). When vaginal wall moves ventrally it presses the urethra just below the vesical neck (DeLancey 1988). Forward contraction of PCMs and adequate tension in urethral supports, i.e. pubourethral ligaments combined with contraction of longitudinal muscle of anus and levator plate, will kink or close the proximal urethra (Ulmsten 1997). However, measurements along the urethra confirms that the adjunctive closure forces are roughly identical throughout the urethra (Thind 1995).

Contrary to other skeletal muscles, the supportive tissue between urethra and levator plate are not completely explained by a ligamentous attachment of the urethra to the pubic bones (DeLancey 1988). The connective tissue has histologically elastic fibers intermingled with collagen (Shafik 1999) and acts like ‘glue’. Muscle relies on that collagenous glue to transmit its contraction to organs. Overstretching of this glue results in dissipation of the muscle’s contraction (Petros & Ulmsten 1990). Defect in this supportive tissue is comparable with a well-trained biceps muscle, if the muscle insertion is inadequate the muscle cannot properly bend the forearm.

On the lateral and ventral aspects of the urethra lie urethral compressor and the urethrovaginal sphincter. Together with the urethral sphincter they form the striated urogenital sphincter (DeLancey 1988). This striated muscle sphincter is morphologically adapted to maintain tone over relatively long periods without fatigue and plays an important role in producing urethral occlusion at rest (Dyson 1995). Because the distal urethra is fixed in position by its attachment to the perineal membrane, contraction of the muscle does not change the urethra’s position, but instead compresses its lumen (DeLancey 1988).
Aging causes a decrease in muscle mass as well as fiber volume and cross sectional area in skeletal muscles (Basu & Basu 2002). Direct intrapartal damage at parturition or in surgical procedures to urethral supporting structures may result in SUI. Transient pudendal nerve denervation can be found after delivery (Allen et al. 1990). It is unclear whether these changes are due to stretching of the pudendal nerve or a direct pressure effect of the fetal head on small branches of the nerve or on the myoneural junction. The role of pregnancy or parturition per se in development of SUI in later life is not clear. Biochemical and morphological analysis have revealed impaired mechanical function in paraurethral tissue in women with SUI at a fertile age compared to continent women (Falconer 1998a). Hormone replacement therapy (estradiol + medroxyprogesteron) seems to reverse connective tissue properties towards premenopausal status (Falconer 1998b), which suggest hormonal influence on continent mechanism.

The dysfunction of any above mentioned factors like nerves, the myoneural junction, connective tissue, muscles, hormones, the vaginal wall, the urethra or the vascular system may predispose a person to incontinence. PFM have a limited capacity to compensate these defects, a fact that is based on the results of clinical studies. In everyday clinical decisions we must speculate when the time for surgical procedures needs to be considered to alleviate the patient’s symptoms.

2.5. Physiological evaluation of the pelvic floor

In the evaluation of pelvic floor disorders including incontinence problems, urodynamic, manometric, electromyographic and imaging studies are complementary.

2.5.1. Urodynamics

Urodynamics provide a means for evaluation of the lower urinary tract and assessing the filling and emptying phases of the bladder. Because there is an overlap in urodynamic findings among incontinent and continent women, the diagnosis of incontinence can not be based on one parameter. A positive cough stress test with a negative cystometry is the most specific technique for detecting urodynamic SUI (Kauppila 1989, Summitt et
al 1992, Swift & Ostergard 1995). Cystometry aims to detect detrusor muscle instability and also hypoactivity, and accordingly, is used in differentiating and classifying various forms of incontinence. Urethral pressure profilometry provides information of urethral resistance and may indentify SUI due to ISD.

Urodynamics have been used to classify the severity SUI (Kujansuu et al. 1984), but its value in this respect is dubious (Meyer et al. 1994). The leak point pressure (LPP) test involves the measurement of intra-abdominal pressure required to overcome outlet resistance and produce leakage. High abdominal pressures, over 90 cm H₂O, has been associated with lesser grades of incontinence in stress incontinent women (McGuire et al. 1993). A low LPP value has been associated with ISD, a subtype of urodynamic SUI caused by the inability of the intrinsic urethral sphincteric mechanism to maintain mucosal coaptation either at rest or in the presence of minimal physical stress. It has been proposed that the diagnosis of this subtype should be a composit of findings including a maximum urethral closure pressure (MUCP), LPP and the degree of stress urethral axis (Bump et al. 1997).

2.5.2. Electrical activity

Electromyography is the study of electrical potentials produced by the depolarisation of muscle fibers. The contraction of striated muscle involves activation of the motor unit inside the muscle and can be recorded as a motor unit potential (MUP). Needle EMG is an accurate method to measure small muscle areas and can contribute to the pathophysiologic diagnosis of pelvic floor disorders in selected patients, in whom a peripheral nervous system lesion is suspected (Flink 1997, Podnar & Vodusek 2001). EMG activity can be monitored during urodynamic investigations to examine the sphincter activity during bladder filling and voiding. Unlike the external anal sphincter where EMG may reveal lower motor neuron lesions, the role of urethral sphincter EMG in subjects (particularly in women) with urinary incontinence is less clear (Podnar & Vodusek 2001).

Although without significant risks needle EMG is uncomfortable and therefore unsuitable for repeated measurements in pelvic floor rehabilitation. Surface EMG is a
non invasive and thus well tolerated method to study muscular function in occupational health and sport medicine (Sihvonen et al. 1991, Kankaanpää et al. 1998). It may also reveal pathological states of the musculoskeletal system (Kankaanpää et al. 1998, Gunnarsson & Mattiasson 1999). Surface electrodes pick up the electrical activity of superficial muscles. The amplitude reflects the number and size of action potentials in the muscle over a given period. The complex signal is analysed by computer.

Because surface electrodes lack selectivity, some electrical activity originating from other muscles also may detected. This phenomenon is referred to as cross-talk and is due to the volume conduction dispersion effect on EMG signal and action potentials on their way to the electrode site (Ferdjallah & Wertsch 1998). The use of surface EMG has also received criticism due to its two main limitations. Surface EMG does not constitute a direct measure of the muscle force. Moreover, the change of electrode position can cause a significant difference in the derived electrical muscle activity (Ferdjallah & Wertsch 1998). As with any test used in the evaluation of patients with pelvic floor dysfunction the EMG should be validated and found to be reliable.

2.3.3. Imaging

Before the ‘hammock’ or ‘integral theory’ of continence mechanism the position of urethrovesical junction was in the focus of incontinence imaging. The placement of a radiopaque chain of metal beads was the first important technique used to study urethral position and mobility. Later ultrasound replaced urethrocytography in the evaluation of the lower urinary tract (Kohorn et al. 1986, Köbl et al. 1988, Kiiholma et al. 1994, Schaeer 1995). Perineal ultrasound gives the same information as urethrocytography in real-time, without exposure to X-rays (Köbl et al. 1988, Virtanen & Kiiholma 2002). However, ultrasound provides only rather fragmentary information about the pathophysiology of SUI and pelvic floor. MRI offers a way to examine the whole pelvis from any angle without exposure to radiation. Moreover the anatomy and pathophysiology of levator ani muscle are possible to demonstrate in living women (Kirschner-Hermanns et al. 1993, Mostwin et al. 1995, Suh et al. 2003). Thus far long imaging times and expensiveness have limited the use of MRI in the evaluation of pelvic floor to scientific purpose.
2.6. Diagnosis of stress urinary incontinence (SUI)

2.6.1. History

The focused history of incontinence symptoms seeks to describe the amount and type of urinary leakage, its associated activities or sensations, and its onset and duration. Other pertinent history includes pregnancies, deliveries, past surgical procedures for gynaecologic or urinary disorders, pelvic radiation, hormonal status, urinary tract infections, and any medication. Among incontinent women symptoms are unreliable indicators of underlying diagnosis. It has been shown that 75% of women with the symptom of SUI have urodynamic SUI, while remaining 25% will have other diagnosis (Jensen et al. 1994).

In order to obtain a precise and reliable urological history which is comparable from patient to patient Kuulansuu and Kauppila (1982) invented and tested a relatively simple questionnaire. The urgency score composed of responses to 10 structured questions. They found that 81% patients with SUI had an urgency score less than 6 compared to 26% of patients with detrusor instability (Kuulansuu and Kauppila 1982). In a later evaluation in all Finnish university hospitals urgency score < 8 had a sensitivity of 86% and a specificity of 48% for SUI, which is in concordance with other published data (Mäkinen et al 1992b, Kuulansuu 1997). A urinary incontinence severity score with 10 specific questions together with the urgency score has been used in Finland to estimate how much incontinence restricts daily life (Mäkinen et al. 1995, Stach-Leupinen et al. 2001).

Short-term (one or two hours) and long-term (12 to 72 hours) pad-weighing tests have been introduced for the objective assessment of urinary incontinence. The long-term test (48 hour), performed by the patient’s home, have a good sensitivity, reliability and compliance (Siltberg et al. 1997, Groutz et al. 2000). Frequency-volume charts offer the possibility of evaluating drinking and micturition habits more objectively (Siltberg et al. 1997). Micturition during the night-time may also discriminate urge and SUI patients (Fink et al. 1999).
2.6.2. Clinical examinations

All women presenting for evaluation of pelvic floor dysfunction should undergo screening for cancer, including a Papanicoulaou smear. Components of general examination that are pertinent to incontinence include an evaluation of nutritional and mental status and mobility. A urinalysis or urine dip stick is also performed to exclude urinary tract infection (Theofrastous & Swift 1998).

Pelvic examination includes the S2-S4 neurological screening test, the evaluation of the estrogen status of the tissues, scars, description of pelvic support defects, vaginal palpation of levator tone during contraction and careful rectovaginal examination to assess sphincter tone, presence of recto/enterocele, fecal impaction or rectal mass. The S2-S4 dermatomes are evaluated with light touch, pin prick and cold sensitivity in the perineum. The integrity of sacral cord reflex is evaluated with the bulbocavernosus and anal wink reflexes, although in 10% of normal subjects, the response is weak to visualize (Theofrastous & Swift 1998).

A sign of SUI is the direct observation of urine loss from the external meatus immediately upon an increase in intra-abdominal pressure. If the loss of urine occurs a few seconds after the increase in intra-abdominal pressure, it is unlikely to be related to SUI, but rather to inappropriate detrusor activity provoked by the stimulus. However, a SUI patient may be able to prevent escape of urine during clinical examination. Jumping, lifting or kneeling can be used as a provocative test.

Urethrovesical junction hypermobility reflects loss of integrity of the urethral anatomical supports, but its contribution to the pathophysiology of SUI is unclear. In the Q-tip test, a well-lubricated cotton tip with local anaesthetic cream is inserted into the bladder at the level of the urethrovesical junction. A change in Q-tip angle of more than 35 degrees between resting and straining has been used to indicate poor anatomic support to the bladder base and urethrovesical junction, although its diagnostic value has been criticized. Non-invasive perineal ultrasound can give the same information of urethrovesical junction hypermobility (Kohorn 1996, Köbl 1988, Caputo 1993, Virtanen & Kiiholma 2002). In the Romney test urethra is fixed on its place by lifting anterior vaginal with a specula and possible leakage is provoked with coughing or Valsalva.
Primary urethral obstruction is rare in women, but may occur after gynecological surgery. Emptying of bladder may be impaired by large prolapse or in some neurological situations. The ability to empty the bladder belongs to basic examination. Postvoid residual urine can be measured with catheterisation or reliably by ultrasound (Rageth 1982, Roehborn et al. 1988). Urethrocystoscopy is part of a complete urogynecological examination and should be performed to rule out restricted bladder capacity, bladder and urethral pathology.

Table 1 shows the basic examinations that should be considered necessary and sufficient before non-surgical treatment for SUI in females (Mouritsen et al. 1997).

Table 1. Scandinavian guidelines for assessment of female incontinence

<table>
<thead>
<tr>
<th>Patient history</th>
<th>- Type and severity of incontinence</th>
<th>- Effect on quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelvic examination</td>
<td>- Other diseases/drugs affecting the lower urinary tract</td>
<td>- Drinking and voiding habits</td>
</tr>
<tr>
<td>Urine test</td>
<td>- Pelvic floor examination</td>
<td>- Pelvic floor examination</td>
</tr>
<tr>
<td>Frequency / Volume chart</td>
<td>- Mucosal atrophy</td>
<td>- Genital descensus</td>
</tr>
<tr>
<td>Stress-test</td>
<td>- Blood, glucose, protein</td>
<td>- Infection</td>
</tr>
<tr>
<td>Pad-test</td>
<td>- Clarifies patient history</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Basis for behavioural advice</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Objectify incontinence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Quantification of incontinence</td>
<td></td>
</tr>
</tbody>
</table>

2.7. Treatment modalities of SUI

2.7.1. Pelvic floor training (PFT)

Pelvic floor exercises first developed by Arnold H. Kegel (1948) form the basis of conservative therapy in SUI. There is strong evidence that PFT is better than no treatment or placebo for women with stress or mixed incontinence (Berghmans et al. 1998, Hay-Smith et al. 2001).
Sixty percent of women perform a correct PFM contraction after brief verbal instruction (Kegel 1948, Bump et al. 1991). The rest have an ineffective effort. Therefore, it seems appropriate that all women should be examined and taught to perform a correct PFM contraction by a health professional person before PFT is undertaken. A physician, therapist or patient herself may evaluate pelvic muscle force and duration of muscle contractions by digital palpation. Laycock (1994) has proposed that in the assessment of PFM strength one should pay attention to power, endurance, number of repetitions, and number of fast (1 s) contractions, and every contraction should be timed. The Oxford grading scale (Table 2) is an internationally accepted muscle grading method. The digital scale has showed a positive correlation with surface EMG readings (Romanzi et al. 1999). Digital palpation is superior to perineometer or cone-retention test as assessing the pelvic floor muscle function (Kerchan-Schindl et al. 2002).

Table 2. Pelvic floor muscle assessment of power. Oxford grading scale.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>1</td>
<td>Flicker</td>
</tr>
<tr>
<td>2</td>
<td>Weak</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Good</td>
</tr>
<tr>
<td>5</td>
<td>Strong</td>
</tr>
</tbody>
</table>

Muscles increase their strength and size when they are forced to contract at tension close to their maximum. High-impact, strain-producing physical exercise training increases the explosive type muscle performance (Shipili et al. 2001) needed also in urethral closure mechanism. In relation to muscle strength, the concept of endurance must be considered, although its effect on muscle hypertrophy is less evident (Shipili et al. 1997). The majority of studies have found that the PFT protocol should include three sets of 8-12 near-maximal contractions, 3-4 times a week (Bø 1995). Most studies have used a 1 to 6 month training period. The current trend is to perform functional training
in different positions and to simulate situations (lifting, coughing, etc) when leakage might occur.

Urethral plugs and supports have been offered for SUI treatment. Temporally, urethral supports give continence in up to 75% of women (Hahn & Milson 1996). Availability, expensiveness and local irritation restrict their use.

2.7.2. Biofeedback (BF)

Biofeedback is a technique in which electronic equipment is used to enable a person to monitor bodily processes and parameters that are normally involuntary or unperceived, so that he or she can learn to modify them. After World War II it was recognized in the rehabilitation of war injuries that audio signals helped patients to perform muscle training more accurately. That finding inspired Arnold Kegel to add BF in PFT (Kegel 1948). The perineometer consists of an air-filled intravaginal balloon attached by a short tube a manometer with a visual display. Various workers have reported considerable success with this technique at office (Wilson et al. 1987, Ferguson et al. 1990). However, for non-acute conditions, such as SUI, an ambulatory perineometer would be more suitable (Jones 1994).

On-line measurement of EMG amplitude can be used for teaching the patient to target the optimal loading (Väätäinen et al. 1995). Real-time measurements on PC screen provide a visual feedback for a patient. BF does not in itself teach a concentric pelvic floor contraction. Instead, BF encourages and improves muscle contractions. Table 3 summarises previous PFT with BF studies in female SUI.

2.7.3. Vaginal cones

Weighed vaginal cones can be offered as an option for incontinence therapy. Cones were introduced as an aid to perform isolated PFM contractions without simultaneous abdominal muscle contraction. Raised abdominal pressure will enhance the downward force of the cone on the pelvic floor increasing the exercise effect (Peattie et al. 1988). In women capable of holding a cone in the upright position, the insertion of a cone leads
to an intermittent type of activation in EMG, reflecting repetitive pushing up of the cone (Deindl et al. 1994). The theoretical basis for cone therapy has been questioned since in some women cones rest on the tail bone, may lie in transverse position or due to anatomical reasons even the slightest cone will slip out (Bø 1995). The use of vaginal cones may improve the strength of PFM, but PFT is more effective treatment for urodynamic SUI than cones (Bø et al. 1999, Herbison et al. 2002).

2.7.4. Electric stimulation

Electric current is used to activate alternative inhibitory pathways in overactive bladder therapy (Fall 1991). Electric stimulation (ES) has been shown to cause minimal strength gain in skeletal muscles compared to voluntary training (Moritani 1979). In addition, and urethral pressure increases significantly more by voluntary contraction than by electrical stimulation (Bø & Talseth 1997). ES is widely used in the incontinence therapy, although its mechanism in the treatment of SUI is unclear.

ES programs can be hospital or clinical based or may include a small home-based stimulator. The most common side-effects and reasons for discontinuation in home-managed electric stimulations are soreness/local irritation in 26% and pain 20% of patients, respectively (Indrekvist & Hunskaar 2002).

In two prospective, double-blind randomized clinical trial ES was no more effective at improving or eliminating the symptoms of urodynamic SUI than was the daily retention of the control probe (Brubaker et al. 1997, Lubec & Wolde-Tsadik 1997). In the study of Goode et al. (2003) incontinence was reduced a mean of 71.9% in the group using behavioral training plus home pelvic floor electrical stimulation, but the effectiveness was not significantly better than using behavioral training and BF in SUI.

2.7.5. Pharmacological treatment

Earlier studies have detected estrogen receptors in the nuclei of the LA muscle (Smith et al. 1993). With enzyme immunoassay techniques no estrogen receptors in the human LA was found (Bernstein 1997). The existence of estrogen receptors in skeletal muscle
tissue of men and women is unclear (Sipilä & Poutamo 2002). Neither local estriol nor three-month cyclic hormone replacement therapy (HRT) affect the amount of urinary leakage (Cardozo et al. 1993, Fantl et al. 1994, Fantl et al. 1996). However, estrogen subjectively relieves lower urinary tract symptoms and is recommended in hypoestrogenic situations during pelvic floor rehabilitation. Also local estradiol administration relieves vaginal dryness, dysuria and dyspareunia without endometrial hyperplasia (Henriksson et al. 1996). The effect of estrogen is probably mediated by connective tissue, mucosa or the vascular network.

The neural reseptors of the urethral smooth muscles are dominated by alpha-adrenoreceptors and a few beta-adrenoreceptors. Phenylpropanolamine (an alpha and beta stimulator) 50 mg twice daily has been used alone or in combined therapy for SUI, especially to cure ISD (Beisland et al.1984). In healthy women noradrenaline (an alpha-adrenoreceptor agonist with beta-receptor stimulation), propranol (a beta 1- and beta 2-adrenoreceptor antagonist), carbachol (a cholinergic agonist) and atropine (muscaric receptor antagonist) seem to have a modest influence on urethral closure function (Thind 1995). Duloxetine, a combined norepinephrine and serotonin uptake inhibitor, is under clinical evaluation (Norton et al. 2002). Animal studies has shown that duloxetine implicates in the central neural control of lower urinary tract function.

2.7.6. Operative treatment

Seventy years ago urinary incontinence was divided two entities. anatomic stress urinary incontinence, which was amenable to surgical correction, and detrusor instability, in which surgery was not advisable (Kohorn 1989). ISD is a severe form of urodynamic SUI associated with weakness of the intrinsic urethral sphincter that is poorly managed by standard surgical approaches for SUI (Bent & McLennan 1998). The aim of over 150 different surgical procedures has been to elevate and return the proximal urethra to its intra-abdominal position, where increases in intra-abdominal pressure rises are equally transmitted to the bladder and urethra. The correction of urethrovesical anatomy in surgery and the following continence has been proven in previous studies (Pentinnen J et al.1989)
Of the various suprapubic operations available for the correction of urodynamic SUI, retropubic urethropexy as described by Burch has been used for years by many surgeons as the primary repair for stress incontinence (Bent & McLennan 1998). The primary objective and subjective cure rate has been as good as 90%, whereas the 10-year objective cure rate declined to 70% (Alcalay et al. 1995). The most common delayed postoperative complications of Burch operation are de novo urge incontinence, voiding difficulties and pelvic organ prolapse (Kiiholma et al. 1993, Alcalay et al. 1995, Bent & McLennan 1998).

As discussed earlier in the section of continence mechanism the urethral support derives from smooth tissues, which facilitate urethral movements in accordance with the movements of the PFM s. Petros and Ulmsten (1990) claimed that elevation of the bladder neck has no anatomical or physiological reason. Instead the form and practice should be mid-urethral support. The integral theory (Petros & Ulmsten 1990) was the starting point for the development of minimal invasive surgical procedures. Thus far the tension-free vaginal tape (TVT) operation is the best documented new method in minimally invasive incontinence surgery. The aim of the TVT procedure is support the continence mechanism with an artificial material without disturbing anatomical structures in pelvic floor. The results of TVT seem to be equal or even better than with Burch colposuspension (Nilsson et al. 2001, Ward & Hilton 2002). Several modifications of this procedure are under evaluation.
Table 3. Summary of eight previous pelvic floor training trials with or without home biofeedback device in female stress urinary incontinence.

<table>
<thead>
<tr>
<th>Author</th>
<th>Design</th>
<th>Device</th>
<th>Subjects</th>
<th>Training period/ Follow-up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burgo et al. 1986</td>
<td>RCT</td>
<td>At office</td>
<td>24 SUI</td>
<td>Training twice a week / 4 weeks Clinical follow up 6 months</td>
<td>Bladder BF 75.6% reduction in incontinence Verbal BF group 51% reduction At six months: Overall, the training effects appear to be maintained</td>
</tr>
<tr>
<td>Wilson et al. 1987</td>
<td>Not randomised</td>
<td>1) PFT in hospital 2) PFT + faradism 3) PFT + interferential therapy 4) PFT at home Pelvectomy</td>
<td>SUI 15 in each group</td>
<td>Training 6 weeks Follow up 6 months, subjective assessment</td>
<td>Hospital retested: improved cured 12/44 Home treatment group: 4/5 noted any improvement</td>
</tr>
<tr>
<td>Ferguson et al. 1990</td>
<td>RCT</td>
<td>At home PFT with and without resistance Intravaginal balloon Audiotape</td>
<td>N=10 with resistance N= 10 without resistance SUI, premenopausal women</td>
<td>Training 6 weeks Postal follow up 12 months</td>
<td>Pressure strength increased in 18/20 Use of balloon did not give better results</td>
</tr>
<tr>
<td>Burns et al. 1993</td>
<td>RCT</td>
<td>EMG and digital integrator Visual BF At office</td>
<td>Total N=123 BF N=40, PFT N=13, Control N=39 Postmenopausal women SUI and N/I</td>
<td>Training 8 weeks Follow up 6 month, subjective assessment</td>
<td>Muscle strength BF&gt;FPT Symptom relief: BF versus PFT not significant BF versus control significant difference</td>
</tr>
<tr>
<td>Berghmans et al. 1996</td>
<td>RCT</td>
<td>EMG Visual and audio BF At office</td>
<td>SUI PFT N=20 BF N= 20</td>
<td>Training 4 weeks 3 times a week / 4 weeks Clinical follow up 4 weeks</td>
<td>After six treatments mean improvement: BF 34.7% PFT 15.1% (p = 0.01) After 12 treatments: mean improvement 55% in both groups</td>
</tr>
<tr>
<td>Hirsch et al. 1999</td>
<td>Not randomised</td>
<td>EMG BF at home</td>
<td>Total N= 23 N=13 SUI N= 20 MI</td>
<td>At home 1/8 min per day 6 months Clinical follow up 6 months</td>
<td>Cure/improvement 28/33 Urge relieved Urodynamics: no change</td>
</tr>
<tr>
<td>Page et al. 2001</td>
<td>RCT</td>
<td>At office Pressure measurements</td>
<td>N= 40 SUI 1) Group (therapy 2) BF</td>
<td>5 times / week 4 weeks (20 times) Clinical follow up 3 months</td>
<td>Free of incontinence episodes BF: 62%, group therapy PFT: 38 %</td>
</tr>
<tr>
<td>Morvé et al. 2002</td>
<td>RCT</td>
<td>At office and at home Pressure measurements BF apparatus at home</td>
<td>Total N= 54 N= 70 SUI N=24 MI</td>
<td>Twice a week 2 months and every second week 4 months, altogether 16 times Clinical follow up 6 months</td>
<td>SUI group: Cure improvement BF: 67% PFT group: 65 %</td>
</tr>
</tbody>
</table>

RCT = randomised controlled trial  SUI = stress urinary incontinence, MI = mixed incontinence, PFT = pelvic floor training, BF = biofeedback
3. **AIMS OF THE STUDY**

The main aim of the present study was to evaluate the role of EMG-based biofeedback in PFT in female SUI patients.

The specific aims were:

1) to study surface EMG signals from PFM s using different arrangements of measuring electrodes (I).
2) to compare PFM activity measured with surface EMG between stress incontinent and healthy women (II.)
3) to conduct a prospective randomized PFT trial for outpatient patients using a BF system for the home and office. To compare primary results after 12 weeks of training (III) and long-standing results after one year (IV).
4) to evaluate the pelvic floor with surface EMG and MRI and to better understand the pathophysiology behind SUI (V).
4. **SUBJECTS AND METHODS**

This study was conducted at the Department of Obstetrics and Gynaecology, Department of Physical Medicine and Rehabilitation, Kuopio University Hospital, and Keski-Suomen magneettikuvuus Ltd, in the city of Jyväskylä. The Ethics Committees of the Kuopio University Hospital and Middle Finland Central Hospital approved the study protocol. For the randomized controlled trial, written informed consent from the subjects was obtained.

4.1. **Subjects**

Study I: Eleven women were tested by the same physiotherapist. Nine of the eleven women were referred by a gynaecological outpatient clinic to a physiotherapist for PFT. They were diagnosed as having stress or mixed incontinence. Two women were continent volunteers. All women were parous with 1 to 4 deliveries. Their mean age was 41 years (min 35, max 54).

Study II: This study included 66 women from the Department of Gynaecology, 31 with urodynamic SUI and 35 controls. The controls were recruited from hospital personnel and from patients in gynaecological unit for sterilization. The women with SUI were aged between 30 and 64 years (mean 48.9, median 51.0 years), their BMI was between 19 and 36 (mean 25.3, median 25.0), and they had deliveries between 0 and 6 (mean 2.5, median 2.0). One woman was nulliparous, two had had both a vaginal delivery and a caesarean section, and the other 33 had delivered solely vaginally. They all had urodynamically diagnosed SUI.

The control group consisted of 35 volunteers aged between 22 and 59 (mean 37.7, median 37.0 years) and their BMI was between 19 and 36 (mean 23.7, median 23.0). Eleven were nulliparous, 21 had had vaginal deliveries (mean 1.7, median 2.0) and three had delivered by caesarean section. On direct questioning none of the controls complained of urinary leakage. The principal investigator conducted this study.

Studies III and IV: The subjects were recruited consecutively at a teaching hospital from the gynecological outpatient clinic during the years 1998-1999. Participants were
urodynamically tested SUI women without previous incontinence operations. They participated in a PFT program after a gynecological interview and examination. Figure 3. Volunteers aged from 21 to 70 years with SUI and the abdominal LPP over 90 cm H₂O were included. Exclusion criteria were genital protrusion beyond the vaginal hymen, inability to understand instructions for home training, pregnancy and any severe disease such as malignancies in the abdominal region, multiple sclerosis and insulin dependent diabetes. In the Study III we analysed the results for 30 women and in Study IV we had followed 35 women for one year.

Study V: In 2000-2001, sixteen female volunteers participated in this study. Eight women, referred from local gynaccologists, had received PFT by the same physiotherapist for their SUI symptoms. They had participated in PFT and achieved an increase in PFM activity, but not complete continence. Their mean age was 44.1 (SD 7.7) years, and all of them had had at least one vaginal delivery. Eight volunteers reported no leakage. Their mean age was 42.2 (SD 13.1) years and three of them were nulliparous.

| General practitioner/gynaccologist |
| Gynaecological outpatient clinic |
| Urodynamics |
| Urodynamic stress incontinence |
| Department of Physical Medicine and Rehabilitation |
| Pelvic floor exercises |
| + |
| Femiscan™ HomeTrainer |
| 12 weeks |
| Pelvic floor exercises alone |
| + |
| 12 weeks |
| One-year follow-up visit |

Figure 3. The study protocol. Studies III-IV.
4.2. Methods

4.2.1. PFT

The written PFT instructions are in Appendix I. The standard instructions were constructed to improve speed, endurance and muscle strength. All patients were given verbal and written instructions for home practice. They were advised to practice for 20 minutes per day five times a week. The patients were advised to practice both at rest and during daily exercises. Patients in the home BF group were advised to note down when they exercised with or without the device.

In the present study BF was used according to Kegel (1948) as an attempt to improve motivation and encourage greater effort during each contraction both in the clinic and during home exercises. A training diary is in Appendix II. In addition, the used device collected data of home training.

Instructions to patients during a concentric contraction were to squeeze and lift the pelvic floor, ‘to hold it there’ for 5 seconds, and then to ‘relax ’slowly before the next measurement.

4.2.2. Surface electromyography (EMG) measurements (I-V)

Studies I-II. A four-channel bipolar EMG system (ME3000P, Mega Electronics Ltd, Kuopio, Finland) was used to record the EMG signal. The continuous raw EMG signal was recorded at a sampling rate of 2000 Hz and band-pass filtered (20-500 Hz), amplified (differential amplifier, common mode rejection ratio > 110 dB, total gain x 412, noise max 3.5 μV RMS in the measuring band), analogue-to-digital converted (12 bit) and stored in a personal computer for later analysis. EMG signals were calculated from raw EMG signals, rectified and expressed as averaged values (μV). The following parameters were calculated: maximum/minimum values per test phase and mean values during contractions from both the right and left side while supine and standing.

In study III-IV Pelvic floor muscle activity was measured at office by a two-channel unipolar EMG system (Inco Trainer, Mega Electronics Ltd, Kuopio). At home patients
used an EMG based biofeedback device (Home Trainer, HMTR, Mega Electronics Ltd, Kuopio) with two-channel unipolar EMG system.

In study I three of the tested probes had six surgical steel electrode plates installed longitudinally into plastic probes. The fourth probe was commercial (Myomed, Enraf-Nonius B.V., The Netherlands) and had 4 electrode plates. In study V EMG measurements were made with by the last mentioned system.

Study I and II: A microtip catheter (Caeltce, United Kingdom, 4F) was inserted to a depth of 2 cm into the anus for measuring rectal pressure during each contraction. The rectal pressure was measured with the four-channel EMG system, but expressed as pressure value (kilopascal).

4.2.3. Urodynamic measurements (II-IV)

Urodynamics were performed in a urodynamic laboratory with a special trained nurse and a trainee in obstetrics and gynaecology. In complicated cases a senior gynecologist was consulted. Before urodynamics the urine was analyzed for bacteria.

Postvoid residual urine was checked with catheterisation. In cystometry, with the patient in a sitting position, the filling rate of the bladder was 50 ml of 0.9% saline solution per minute. Cystometry was first continued up to a volume of 300 ml. MUCP was measured with 300 ml fluid in bladder. After that cystometry was proceeded to 500 ml or to maximal capacity. During cystometry the following parameters were analysed: first sensation, desire to void, urge, and the possible increase of bladder pressure.

During urethral pressure profilometry the urethral pressure was first recorded at rest. Secondly the patient was asked to cough 4 to 6 times with force. If no leakage was noticed with the bladder volume of 300 ml, coughing was repeated with the bladder volume of 500 ml. The MUCP was registered first at rest and while coughing also the abdominal LPP was recorded.

Urodynamic exclusion criteria (MUCP < 20 cm H₂O, LPP < 90 cm H₂O, increase in detrusor pressure >10 cm H₂O) were chosen because they are known to be associated with detrusor instability or ISD (Bump et al. 1997).
4.2.4. Pad test (III IV)

Twenty-four hour home pad weights were conducted before trial entry and after the last clinical visit. Women chose a typical day that mirrored their average level of activity. Appendix III.

4.2.5. Questionnaires (I-IV)

In the evaluation of patient history the urgency score described by Kujansuu and Kauppila (1982) was used. The subjective outcomes were measured using the leakage index described by Bø (1994b), and they were recorded before the treatment and at 12 weeks. The leakage index contains thirteen types of physical exertions that trigger urinary leakage in women with SUI. An urogynaecology nurse conducted the pad test and the leakage test. Appendix IV.

4.2.6. Magnetic resonance imaging (MRI) (V)

MRI was performed with a 1.5 T GE Signa CV/i high-speed scanner with real-time fluoroscopic imaging possibilities. Morphological T1- (TR 540, TE 15, ET 2) and T2- (TR 4800, TE 96, ET 16) weighted fast-spin echo images were taken in the axial, coronal, and sagittal planes. Fluoroscopic imaging was carried out in the corresponding planes with T1-weighted fast gradient echo and T2-weighted single shot fast spin echo sequences at a speed of about one frame per second.

Participants were scanned in the supine position with knees lightly supported. The participants were instructed to contract pelvic floor periodically during fluoroscopic scanning.

Images were evaluated on a workstation by an experienced radiologist, who was blinded to the clinical symptoms and the EMG findings.

From the axial images, the thickness of the pubococcygeal portion of LA was measured from both sides at the level of proximal and distal urethra. The reference point
for proximal measurements was the urethrovesical junction and the caudal edge of symphysis for distal measurements.

Furthermore, the movement of pelvic floor was measured from sagittal and axial fluoroscopic video imaging. From sagittal images, the line between the coccygeus and the symphysis pubis was used as a reference when measuring the elevation of the centrum tendineum perinei (perineal body) during voluntary contractions. The difference of the distance of the perineal body from the reference line between contraction and relaxation was registered. The composite axial image was used to calculate the range of displacement of perineal body from symphysis. The line between obturator internus muscles and perincal body was used as a reference line when analysing the deviation of the perineal body.

4.3. Statistical analysis

The SPSS program for Windows (version 7.55-11) and Statistica for Windows (Version 6) software were used for statistical analysis. The level of significance was set equal to 0.05. The intent-to-treat principle was used in the randomised trial.

In Study I, the Wilcoxon’s test and Friedman’s test was used to find differences between probes. The Spearman correlation coefficient test was used to compare consecutive contractions with the same probe.

In Study II, analysis of variance and regression analysis was used for evaluating the effect of age, parity, episiotomies or BMI on the electrical activity of PFM.

In Study III, the data analysis was based on analysis of covariance and analysis of variance for repeated measures. We used analysis of covariance to test the change between the baseline and follow-up using baseline as the covariate. This was made in order to study the adequacy of randomisation. Analysis of covariance was used for the pad test and the leakage index. If the covariate was not significant, analysis of variance for repeated measures was carried out. The imputation of missing data was needed for the 12-week pad test for one control patient; the missing observation was imputed by the baseline value. The results were identical without and with the imputation.
In study IV, the description of the data was made using cross tabulations and percentages for dichotomous variables, and means (SD) and medians for continuous variables. Differences between groups for dichotomous variables was assessed with the chi-square test. Differences for the changes within subgroups over time was assessed with the Wilcoxon-rank test. The multivariate data analysis was based on logistic regression with surgery for stress incontinence as the dependent variable and possible risk factors as the explanatory variables. The possible risk factors were device and the changes of the EMG measurements and leakage index over time. The continuous variables were analysed in a logarithm-transformed form. A forward stepwise model was used, and the limits to enter and to remove variables were set equal to 0.10 and 0.15, respectively. The imputation was carried out by replacing the missing observations by the respective sub-group means.

The main researcher was blind to the treatment conditions.

In study V, mean values were compared statistically between the two groups using Mann-Whitney test and the values were expressed as the mean (SD). Pearson’s correlation coefficient (r) was used to compare EMG values and the thickness of PCM.
5. RESULTS

5.1. Comparability of the study groups

In Study II the main difference between SUI and control groups was age. With urodynamic SUI patients mean age was 48.9 years (range 30-64) and in controls 37.7 (range 22-36), respectively. Although stress incontinent women had more vaginal deliveries (mean 2.5) than controls (mean 1.7), the difference was not significant. In respect with BMI the difference was not significant.

Figure 4. demonstrates the enrollment of the study patients to the randomised trial. Prognostic comparability at baseline is not guaranteed by randomisation of small groups of subjects and prognostically relevant differences might occur by chance (Berghmans et al. 1998). The number of randomised patients was smaller than expected, and covariates were needed in the analysis of leakage index and pad test. Characteristics of patients in PFT trial are in Table 4.

Table 4. The characteristics of the patients in PFT alone vs PFT with BF trial. Values are means (SD, min-max) unless stated otherwise.

<table>
<thead>
<tr>
<th></th>
<th>Biofeedback N = 16</th>
<th>PF N = 19</th>
<th>T-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>51.4 (6.1, 35-61)</td>
<td>49.4 (9.5, 31-69)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Body mass index</td>
<td>26.4 (4.1, 21-36)</td>
<td>25.8 (4.2, 21-36)</td>
<td>Not significant</td>
</tr>
<tr>
<td>No of vaginal deliveries</td>
<td>2.1 (1.3, 0-5)</td>
<td>3.0 (1.7, 0-7)</td>
<td>Not significant</td>
</tr>
<tr>
<td>No of cesarean sections</td>
<td>0</td>
<td>0.1 (0.3, 0-1)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Duration of symptoms (years)</td>
<td>8.5 (8.6,1-30)*</td>
<td>6.6 (3.9,1-16)**</td>
<td>Not significant</td>
</tr>
<tr>
<td>Leakage index at beginning</td>
<td>44.3 (10.8, 27, 70)</td>
<td>37.8 (12.1,10-58)</td>
<td>Not significant</td>
</tr>
<tr>
<td>No of postmenopausal women</td>
<td>9</td>
<td>12</td>
<td>Not significant</td>
</tr>
<tr>
<td>Urgency score</td>
<td>6.1 (2.7, 2-11)</td>
<td>7.6 (3.3, 2-14)</td>
<td>Not significant</td>
</tr>
<tr>
<td>Incontinence incontinence severity score (%)</td>
<td>46.9 (19.2, 15-95)</td>
<td>50.8 (18.2, 10-58)***</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

*N = 15, ** N = 17, *** N =18
Figure 4. Flow chart showing stages in the study protocol and the number of participants.

5.2. PFM activity measurements

5.2.1. The role of different probes in the EMG measurements of PFM activity (I)

PFM activity could be measured from both the right and left side with four different probes. Despite some numerical differences between values measured with different probes, a comparison of pair differences revealed no statistical significances. A strong
correlation was observed between the EMG values from consecutive measurements with all probes (p = 0.014-0.000). The spearman correlation coefficients (r = 0.86-0.97) for the second and third vaginal flicks for each probe are shown in Table 5.

Table 5. Spearman correlation coefficient for second and third vaginal flicks for each probe

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>r</td>
<td>0.86</td>
<td>0.92</td>
<td>0.84</td>
<td>0.97</td>
</tr>
<tr>
<td>p</td>
<td>0.014</td>
<td>0.001</td>
<td>0.009</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

5.2.2. Age, parity and episiotomies as determinants of PFM activity (II)

The calculated mean EMG values (µV) of three rapid contractions in supine and standing positions are shown in Table 6. After adjustment for age, the difference between the incontinent and healthy groups was 3.7 µV, with mean values while standing of 13.7 µV, and 17.4 µV (p = 0.094), respectively.

The regression analysis was performed in the whole study population and the mean values in both supine and standing positions were dependent on age (p = 0.004 and p = 0.009), respectively.

The mean values were not significantly dependent on parity (p = 0.116 while supine, p = 0.365 while standing), episiotomies (p = 0.728, p = 0.905) and body mass index (p = 0.056, p = 0.302). The supine position mean values were slightly dependent on vaginal deliveries (p = 0.035), but not in the standing position (p = 0.348). Among healthy the correlation between mean values and vaginal deliveries was significant (p = 0.04) while supine.
Table 6. Vaginal muscle activity (μV) in supine and standing positions among the study groups.

<table>
<thead>
<tr>
<th></th>
<th>Controls</th>
<th>SUI</th>
<th>95% Confidence Interval of the</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 34</td>
<td>N = 31</td>
<td>Lower</td>
</tr>
<tr>
<td>Muscle activity</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>(supine)</td>
<td>19.5 (8.4)</td>
<td>17.0 (10.5)</td>
<td>-2.2</td>
</tr>
<tr>
<td>Muscle activity</td>
<td>18.2 (8.7)</td>
<td>12.9 (5.9)</td>
<td>1.6</td>
</tr>
<tr>
<td>(standing)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.3. **Home BF recordings (IV)**

In the PFT with BF group, a mean of 68 (range 10-131) home training sessions were recorded by the EMG guided biofeedback measurement device. In addition to those recordings, patients had written down an average of 46 (range 6-76) days when they had exercised without the device. In the PFT group, 2 out of 19 subjects did not return the training diary. The mean number of training days was 61 (range 21-87) in the PFT group.

5.4. **Objective outcome after intensive training (III, IV)**

Primary results after 12 weeks’ intervention: When analysing the posture PFM activity values, there was a significant change over the time (p < 0.001) and the interaction between the groups and the period was significant (p = 0.024). Figure 5. demonstrates that in the PFT group there was no actual change, but in the PFT with BF group the increase from the baseline was very clear.

With respect to the standing PFM activity values, there was a significant increase over the periods (p < 0.001), but it was identical in the PFT and the PFT with BF groups
(interaction \( p = 0.565 \)). The example of EMG recordings before and after training is in Appendix V.

The study groups differed with respect to the baseline in the pad test: the covariate was significant \((p < 0.001)\). Accordingly, we analysed the change over time and used baseline values to adjust for change. The crude change means were 26.4 g for the PFT group and 9.1 g for the PFT with BF group. After adjusting they were 18.1 g and 17.3 g, respectively. The difference was not significant \((p = 0.907)\).

![Graph showing EMG activity over time for Controls and Biofeedback groups.](image)

Figure 5. Changes in pelvic floor muscle activity after 12 weeks’ training.

Fourteen women underwent surgery or were waiting for an incontinence operation. There was 5/16 (31.3\%) operated in the home PFT with BF group and 9/19 (47.4\%) in the PFT alone group. The difference was not statistically significant. Two of women in the non-operated PFT group had continued PFT with the home BF device on their own initiative.
5.5. **Subjective outcome after intensive training (III, IV)**

Primary results after 12 weeks’ training: With respect to the leakage index, the analysis of covariance was also needed. The baseline as the covariate was significant ($p = 0.003$). The crude change in means was 0.33 for the PFT group and 10.6 for the PFT with BF group. After adjusting, the means were 2.1 and 8.8, respectively. The difference was close to statistically significant ($p = 0.068$). There was no actual change in the PFT group, but for the PFT with BF group the baseline mean was clearly higher, and after 12 weeks they experienced a clear decrease. Only the non-operated hometrainer group achieved a significant reduction in the leakage index during training period ($p = 0.055$).

Logistic regression analysis showed that the change of leaking index was associated with the operation. Decrease in leakage index decreased the risk for an operation OR 0.033 (95% confidence intervals 0.001-1.085, $p = 0.056$).

Two patients discontinued the use of the home training device and continued training without it. They were both postmenopausal, and they felt the vaginal probe to be uncomfortable. In addition, five other patients mentioned they had pain while training, three in the PFT group and two in the PFT with BF group. Three of these women were premenopausal.

Two women in the PFT group informed that they had tested hometrainers on their own initiative between intensive treatment period and one-year follow up. One woman in the PFT with BF group had tested electric stimulation. With another woman in the PFT group, the incontinence operation went successfully, but after one month she was incontinent again. She did not want a re-operation or any other new treatment, however. In the interview at one-year follow up, 67% of women considered PFT effective or very effective, and none considered home PFT with BF harmful.

5.6. **Findings in static and dynamic MRI (V)**

Normal findings and variations in pelvic floor configuration are demonstrated in the MRI images in Appendix VI. In addition, in Appendix VII contains MRI images of a normal pelvic floor with a test probe (study I-II) *in situ*. In sagittal MRI images, the
iliococcygeus muscle appears as dome shaped at rest. During voluntary pelvic contractions, the muscle becomes more convex in an upward direction. During contraction, LA muscle moves ventrally and cranially simultaneous with the bladder base. The mean movement was 2.4 mm (range 0-6.0 mm) among all women and 2.2 mm (range 0-5.4) in the incontinent and 2.7 mm (range 0-6.0) in the continent groups in the sagittal image. In the axial image, the values were 1.9 (range -2.3-5.9), 2.4 (range 0-5.9) and 1.3 (range-2.3-4.8) mm correspondingly. The differences between groups were not significant.

The co-ordination of muscles during muscle contractions was analysed from axial sections. Although all the women had been taught how to perform the contractions of PFM, two women used mostly abdominal and gluteal muscles during voluntary contraction. The axial images showed how the perineal body becomes elevated during a voluntary contraction. In three cases, the perineal body deviated to the left during voluntary contractions, indicating better muscle activity on that side and in two cases the perineal body deviated to the right side. If the difference between right and left side elevation was over 2 millimetres, this was considered as a deviation.

In the axial images, the intact PCM appears as a symmetrical V-shaped form and the muscle contracts symmetrically. Variations of the pelvic floor were seen both in incontinent and asymptomatic women. Asymmetry in thickness and loss of fiber continuity in the pubococcygeal part of levator ani were the most obvious findings.

A statistically significant difference between continent and asymptomatic women was detected in the thickness of distal part of PCM (p = 0.04) and the EMG values on the left side (p = 0.03). Women with three deliveries had a thinner distal part of the PCM than nulliparous women on the right (p = 0.03) and on the left (p = 0.05) sides. The thickness of the distal part of the PCM correlated significantly with EMG values: on the right side, r = 0.49 and on the left r = 0.53. No statistically significant correlations were noted between EMG values and PFM lifting.
6. DISCUSSION

6.1. Subjects

All subjects in this series of studies (n = 128) were adult women (age range 22-69 years). The majority of patients had urodynamically tested stress incontinence. Controls were regarded as asymptomatic when they reported no urinary leakage during strain on direct questioning. No invasive urodynamic test were necessary for healthy controls.

Without urodynamic testing we might have had more participants enrolled in the home BF trial. On the other hand, without urodynamics a quarter of incontinent patients do not get a precise diagnosis (Jensen et al. 1994). Women with SUI symptoms, but with a negative stress sign in urodynamic testing may have minimal SUI and will most probably benefit from PFT (Mouritsen et al. 1991).

We had pre-, peri- and postmenopausal women participating in this study. A positive hormone status may influence PFT outcome (Mouritsen et al. 1991). In postmenopausal women muscle performance, muscle mass and muscle composition were improved by HRT in a randomized placebo-controlled physical exercise study (Siplä et al. 2001), although the presence of estrogen receptors in skeleton muscles is uncertain. Estrogen per se does not have an effect on the amount leakage of urine (Faul et al. 1996). Our patients were allowed to continue their HRT, and estrogen was recommended during PFT if vaginal dryness existed.

The study population in Study I was heterogeneous as regards incontinence symptoms. Intraindividual comparisons were made between different probes. In Study II controls were recruited from hospital personnel and from patients in gynecological unit for sterilization. Healthy parous and nulliparous women were easy to recruit, and many of them were curious to know of their body function. Older healthy volunteers were difficult to find. It would have been logical to perform MRI on the participants of the home training trial. Unfortunately dynamic MRI facilities at the beginning of this study were limited.
6.2. Surface EMG measurements

The pelvic floor is invisible inside the body. The contraction of most voluntary muscles involves joint movement, whereas PFM contraction does not. PFM contraction is palpable and causes movement of the perineal body. Surface EMG measures superficial muscles, but also adjacent muscles may interfere to measurements (Ferdjallah & Wortsch 1998). In the first two parts of this study we used visual observation, palpation, and a rectal probe to confirm voluntary PFM contraction, which was later also visible on dynamic MRI imaging.

Test-retest data are mainly based on correlation analysis, which is problematic to interpret (Lose et al. 1998). We compared consecutive measurements during same session. It would be more relevant to compare measurements from consecutive sessions, but a learning effect is then possible.

The quality of the EMG signals was good. Only in one case (in Study II) were no acceptable results obtained. There were artifacts, such as spikes, but they were manually deleted.

Our findings corroborated one previous study, which showed that all three groups of incontinence (mixed, urge and stress) had a successive decrease of the PFM EMG activity with increasing age (Gunnarson & Mattiasson 1999). A decrease in the synthesis rate of myosin heavy chain and actin, the key contractile proteins, may be responsible for reduced muscle strength (Basu et al. 2002). Although the continence mechanism is complex, the weakness of PFM related to aging may contribute to incontinence.

The aim of PFT should be to increase both muscle strength and endurance (Laycock 1994, Bø 1995). At the beginning of PFT signals may be short lasting and low in amplitude. A good long-lasting contraction gives a sustained signal that is high in amplitude. Thus on-line measurement of EMG amplitude can be used for teaching the patient to achieve the optimal loading (Väätätinen et al. 1995). In our clinical trial BF was used to improve motivation and control home training.

With the aid of recordings from the home device the compliance of the patients could be monitored. Our patients had excellent compliance, with a mean of 68 recorded
training sessions with training diary remarks. Those recordings and the evidence of increased muscle activity convinced us that overall the patients had done their best. Thus this kind of method may prevent the frustration of long-standing training. Without follow-up, on the other hand, discontinuation of PFT is quite common (Ferguson et al. 1990).

6.3. **Short-term effect of PFT**

Today there is no agreement about the most appropriate outcome measurements for urinary incontinence events. The Standardization Committee of the International Continence Society recommended use of measures of urinary leakage and self-report to evaluate the treatment effect of PFT (Lose G et al. 1998). Although the status of muscle activity as an outcome measure is unclear, pelvic activity was used in our study to confirm the effectiveness of PFT. Experiences of other rehabilitation studies convinced us to use EMG as a measure of muscle strength gain (Moritani & DeVries 1979, Sihvonen et al. 1991, Väätäinen et al. 1995, Kankaanpää 1998).

This study demonstrates the efficacy of PFT alone and in combination with a BF device in increasing muscle activity. Our results corroborate randomised studies by Burns et al. (1993) and Bergmans et al. (1996), who found a significant increase in pelvic muscle activity after office-based BF-training.

A reduction in leakage index and the pad test can be achieved with PFT. Although a complete cessation is not always achieved, many women consider themselves cured (Bø et al. 1999). In our study, both groups achieved a decrease in the amount of leaked urine. The leakage index questionnaire also contained questions about social activity (Bø 1994b). We considered three months to be too short to achieve significant changes in social activity, and those questions were excluded from analysis.

6.4. **Long-term effect of PFT**

Most studies have used a three to six month training period. There are few studies with a long follow-up time. Mouritsen et al. 1991 reported that with an intensive pelvic floor
exercise programme 47% of incontinent women were cured or improved one year after completion of the exercises. Subjective results were confirmed with a 24-hour pad test. In concordance with our findings, between completion of the 12-week exercise program and one year follow up there were additional improvement in continence status. In a five-year follow up Bø & Talseth (1996) reported that 3/23 patients had been treated surgically, and 70% were satisfied and did not want further treatment. Their patients participated initially in a six-month training program. It only can be speculated should PFT be lifelong, since there is evidence of impaired PFM activity during aging.

Wilson et al. (1999) concluded that improvement was more commonly reported than cure in PFT studies. In the study of Mørkved et al. (2002) the cure rate was higher measured by the pad test than reported by the women. Discrepancy between objective and subjective assessments of outcome may lead to use of an improvement rate. Campbell et al. (2003) proposed that in randomized controlled rehabilitation trials an independent interviewer should be used to collect patient based outcome measures and to determine whether an intervention is effective. In this study the physiotherapist collected one-year interview data, but the main investigator was blind to the intervention procedure.

As far as we know, socio-economic measures have not been reported in PFT trials. Cost-effectiveness analysis should contain both direct, cost in the routine care, diagnosis, treatment, and management of adverse consequences, and indirect costs, like being incontinent (Lose et al. 1998). A crude estimation of direct costs showed that even only with a 60% cure rate it is less expensive to first try conservative treatment, and then if it fails, to perform an incontinence operation. We share the opinion of previous researchers that intensive PFT should precede surgery, since exercises have a long-lasting effect in as many as 70% of patients (Mouritsen et al. 1991).

Our findings do not discount group therapy, which has also benefits in PFT (Bø & Talseth 1996, Pages et al 2001). However, in a country with long distances and limited resources in health care, a supervised home training system might be an option.

In a review of randomized controlled trials DeKruif and Van Wegen (1996) found, that exercise therapy using myofeedback is an effective method for women with SUI and is more effective than solely exercise therapy. In contrast, another meta-analysis
found that BF as an adjunct PFT does not seem to be more effective than PFT alone, although this strategy might be more effective than PFT alone in the first period of treatment (Berghmans et al. 1998). The setting in this study was pragmatic. This study compared standard or low-intensity PFT at home to high-intensity training at home with an EMG-based BF system. Further work under similar circumstances and with a larger sample size is needed before our findings can be generalized. The positive effect of BF at the beginning of therapy is in concordance with previous findings (Bentsen et al. 1997, Berghmans et al. 1998).

6.5. The role of MRI findings in PFT

With the aid of MRI imaging recent studies have found that in living individuals the levator ani is shortened, elevated in position, and has a cranial and medial convexity (Strohbehn et al. 1996, Tunn et al. 1998). The voluntary contraction of levator muscle forces the vagina and rectum ventrally and cranially and this leads to the compression of the urethra against the symphysis. Perineal ultrasound allows also static and dynamic evaluation of bladder neck (Schaer et al. 1995). In contrast to ultrasound, dynamic MRI permits the investigator to observe the whole levator plate movement during contractions and strain.

The setting of this MRI study was experimental. This study revealed minor differences between incontinent and asymptomatic patients, perhaps due to the small number of cases. However, we did detect a correlation between the EMG values and the thickness of the distal part of the pubococcygeal muscle and the partial loss of levator ani muscle, which may explain why the increase of muscle activity achieved in PFT is incomplete in some cases.

A significant difference between the thickness of distal part of PCM was found between nulliparous women and women with three deliveries. In Finland, the right medio-lateral episiotomy is used. Since this was cross-sectional pilot study, no general conclusions on the effect of episiotomy can be drawn. Tunn et al. (1999) followed the levator ani muscle’s configuration postpartum for 6 months. They found that levator ani thickness showed interindividual variations, and a complete loss of levator ani tissue
was found in one of their 14 subjects. On the other hand, there are number of variations not attributable to limitations of the measuring technique in the pelvic floor configuration among healthy nulliparous women (Chou & DeLancey 2001, Tunn et al. 2003).

One advantage of MRI is that it allows a detailed evaluation pelvic floor in living subjects. In our study all scans were taken in the supine position. A standing or sitting position would be more natural. One experiment has, however, confirmed that thickness of levator sling and width of the levator hiatus are identifiable and stable in the supine and the sitting positions (Fielding et al. 1998).
7. **CONCLUSIONS**

The following conclusions can be drawn from the results obtained in the present study:

1. Surface EMG is a patient-friendly method that allows investigation of PFM activity at rest and during muscle contraction. The form and arrangement of the electrode plates and the type of probe may affect EMG values. Multichannel modality enables simultaneous measurement of PFM activity from the right and left side, but proper software is needed to understand the complex EMG signal and to use it in rehabilitation.

2. Although the EMG device that was tested showed a tendency for lower PFM activity in incontinent patients than in controls, especially in the standing position, its value as a diagnostic tool is not well established. However, EMG-based biofeedback can be used in pelvic floor rehabilitation when keeping in mind that the PFM activity increase during training must be compared with the patient’s own baseline level. The EMG activity of pelvic floor muscle decreases during aging, which is compatible with the aging process in other skeletal muscles.

3. In a one-year follow up the success rate, i.e., cured or improved and thus avoiding surgery, in PFT with home BF was quite good, 68.8%. Although our pilot study was underpowered to show a statistical difference, the difference between the PFT alone and the PFT with home BF groups may nonetheless be clinically relevant. The changes achieved in PFM activity and leakage index were noted already after 12 weeks of intensive therapy in the non-operated PFT with BF group, which may indicate that the effect of PFT may be assessed earlier with the hometrainer than with PFT alone.

4. Static and dynamic MRI images of the pelvis provide more anatomical information than can be obtained with any other previous method. This study
revealed that a factor contributing to the poor pelvic floor muscle EMG values may be a thin levator sling. The most obvious defects seen in the pubococcygeal muscle were asymmetry in thickness and loss of fiber continuity. This is important knowledge when planning further treatment for SUI patients.
8. REFERENCES


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