

Medicare Coverage Policy ( NCDs)  
Pelvic Floor Electrical Stimulation for  
Urinary Incontinence (#CAG-00021N)  
Technology Assessment

March 2000

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PELVIC FLOOR ELECTRICAL SIMULATION IN THE TREATMENT OF  
ADULT URINARY INCONTINENCE

OBJECTIVE

For patients with the most common types of urinary incontinence, first-line therapy consists of behavioral treatments such as bladder training and pelvic floor muscle exercises (PME). Pelvic floor electrical stimulation (PFES) is another alternative for conservative treatment of patients with urinary incontinence. This technology assessment reviews the available evidence to determine whether PFES improves health outcomes of patients with urinary incontinence. PFES is compared with placebo treatment, other conservative treatments for incontinence (PME, bladder training, PME using vaginal cones, medication), and as an adjunct to PME. Stress incontinence and urge incontinence are the most common types of urinary incontinence treated with behavioral techniques and are the main focus of this assessment. The use of PFES for treatment of post-prostatectomy incontinence is also addressed in this assessment, as this is a common cause of incontinence in the Medicare population. The treatment of urinary incontinence that is due to neurologic injury or disease is not addressed as part of this assessment.

BACKGROUND

Urinary Incontinence

Urinary incontinence is a common problem, estimated to affect 13 million adults in the U.S., and to account for costs exceeding \$15 billion per year (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). In 1994 dollars, it was estimated that 11.2 billion was spent on the direct treatment of incontinence, and \$5.2 billion on associated nursing home costs. For older adults living in the community, the prevalence of urinary incontinence is between 15 and 35%, with women affected twice as often as men. The condition is even more common among residents of nursing homes, where more than half of the residents

experience urinary incontinence. In addition, urinary incontinence has been cited as one of the major precipitants for placement in a nursing home (Ouslander et al. 1982). Thus, among the elderly Medicare population, this condition is common, and associated with a high burden of illness, high costs, and a substantial negative effect on quality of life.

The two major categories of urinary incontinence addressed in this Assessment are stress incontinence (SI) and urge incontinence (UI). These are also the primary categories of incontinence that PFES is intended to treat. Stress incontinence is characterized as loss of urine that occurs with activities that increase intra-abdominal pressure, such as coughing, sneezing, or lifting heavy objects. The majority of stress incontinence is acquired, through weakening of the pelvic floor support structures as a result of aging, child birth or other factors (NIH Consensus Statement 1989). Urge incontinence occurs when patients are unable to hold urine in response to the urge to urinate. This most commonly results from uninhibited bladder contractions as a result of instability of the detrusor muscle. Often, features of both stress and urge incontinence co-exist, in this case the term "mixed incontinence" (MI) is used.

Within the categories of stress and urge incontinence, further diagnostic distinctions can be made, and the response to various treatment options may theoretically differ with the underlying disorder present. The underlying abnormality in stress incontinence can be either hypermobility of the bladderneck, intrinsic deficiency of the urinary sphincter, or both (Fantle et al. 1996; Urinary Incontinence Guideline Panel 1992). For urge incontinence, the etiology is not understood, although subcategories are distinguished as detrusor instability when no underlying cause is identified or as detrusor hyperreflexia when an obvious neurologic cause such as a cerebrovascular accident is evident.

Post-prostatectomy incontinence is also a common condition among elderly Medicare patients, especially as detection and subsequent treatment of prostate cancer increases. Post-prostatectomy incontinence may be predominantly stress or urge incontinence, depending on the indication for surgery and the type of procedure performed, and many patients may be good candidates for pelvic floor muscle exercises (Johnson and Ouslander 1999). Two recent large cohort studies examined the long-term rates of incontinence following radical prostatectomy. Stanford et al. (2000) followed 1,291 men for 18 months and reported that 8.4% of patients were incontinent at that time point. Catalona et al. (1999) reported a similar incontinence rate of 8% in 1,870 men followed for 2 years. Some evidence exists that treatment of post-prostatectomy incontinence with PME is efficacious. A recent randomized controlled trial of PME in this group of patients reported a significantly increased rate of continence at 3 months in the PME group as compared to the control group (88% versus 56%,  $p < 0.001$ ) (Van Kampen et al. 2000).

Numerous other etiologies of incontinence exist. Reversible causes, such as urinary tract infection or medications, are managed by treating the underlying cause. A variety of neurologic disorders or injuries can interrupt innervation of the bladder and lead to incontinence. Overflow incontinence occurs when the bladder cannot empty normally and becomes overdistended, such as occurs with bladder outlet obstruction as a result of

prostate hypertrophy. Functional incontinence refers to the situation where no physiologic pathology is present, but incontinence occurs as a result of immobility or severe cognitive dysfunction.

For stress, urge, and mixed incontinence, a number of treatment options exist, ranging from behavioral measures to surgical procedures. In general, a staged approach to treatment is most patients, beginning with the most conservative techniques, and progressing to pharmacologic or surgical treatments if initial measures are not successful (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). The Agency for Health Care Policy and Research (AHCPR) issued the most recent guidelines for the management of urinary incontinence in 1996 (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). These guidelines recommend that a trial of behavioral intervention be applied to all appropriate patients prior to the use of drugs or surgery.

### Behavioral Treatments for Urinary Incontinence

Behavioral treatments for urinary incontinence, which may include toileting assistance, ladder training, and/or pelvic floor muscle exercises (PME), are generally the first-line treatment for stress or urge incontinence. The AHCPR published guidelines for the management of urinary incontinence in 1996 (Fantl et al. 1996). These guidelines support the use of behavioral therapy as first-line treatment in most patients with stress incontinence or urge incontinence.

The simplest behavioral treatment, toileting assistance, is intended for patients who are disabled or cognitively impaired, and who require the assistance of a caregiver for their activities of daily living. For other categories of patients, behavioral treatments may consist of bladder training, pelvic muscle exercises (PME), or a combination of the two. Behavioral techniques are generally tailored to the specific etiology of incontinence. For stress incontinence, PMEs are the main component of treatment. PMEs derive from the Kegel exercises developed in the 1940s and 1950s. Patients are taught to contract these muscles for a defined time period, for example, 10 seconds, followed by a period of relaxation. This is repeated at a prescribed frequency, which increases overtime. The AHCPR guidelines recommend that contractions be performed 30-80 times per day for a period of 8 weeks or longer (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992).

For patients with urge incontinence, bladder training is employed, with or without PME. The primary goal of BT is to teach the patient to inhibit contractions of the detrusor muscle, thereby reducing the sense of urgency associated with uninhibited bladder contractions. Education in the form of written, verbal, or visual instruction is provided. Patients are placed on a systematic voiding schedule that allows the bladder to adjust to increasing levels of distension. The program may also use distraction or relaxation techniques to achieve these goals. Control of fluid intake is sometimes used to aid in adhering to a voiding schedule.

Treatment with PME or bladder training requires that patients be cognitively intact and motivated to learn and practice the techniques. This was demonstrated empirically by Castleden et al.(1985). These authors studied the factors that were predictive of success with these treatments in an elderly population, and reported that mental ability was the factor most strongly related to a positive outcome.

The delivery of behavioral treatments is not standardized. The method and intensity of instruction for bladder training and PME may vary. The method of delivery may range from brief verbal instruction by a physician in the office setting, to written materials, to individual session(s) with a clinical specialist trained in delivering this treatment. The intensity of the treatment will vary both as a function of the number of training sessions employed, and with the frequency with which the patient practices the techniques at home. A trial comparing home exercise alone to home exercise with weekly training sessions found that the more intensive PME training regimen was more effective (Bo et al. 1990).

Although behavioral techniques are widely accepted as the most appropriate first-line therapy for stress and urge incontinence, there are few controlled trials of these techniques in the literature. However, several controlled trials of PME exist, and collectively these trials establish the effectiveness of PME. In a randomized, controlled, trial, Wells et al. (1991) treated 82 patients with PME and 75 patients with phenylpropanolamine, a standard first-line medication for stress incontinence. This study reported found outcomes of PME to be similar to drug treatment, with 77% of the exercise group and 84% of the drug group reporting improvement. Burns et al.(1993) compared both PME alone and PME plus biofeedback to a waiting list control group. Both treatment groups had a significantly greater improvement (54% and 61% respectively) than the waiting list control (6%,  $p<001$ ). This limited evidence suggests that PME is more effective than no treatment and roughly equivalent to medications for these patient groups.

### Pelvic Floor Electrical Stimulation

Electrical Stimulation is a collection of treatment modalities (Bosch and Groen1995; Haber1986; Moore et al.1995). Each is characterized by the physiological site of stimulation and the type of electrical impulses delivered. Implantable techniques refer to the internal placement of electrodes with a mechanism outside the body to assist the patient in the control over micturition. These implantable devices are not included as part of this Assessment.

Non-implantable electrical stimulation is a distinctly different class of treatment. In these cases, stimulation is usually delivered by vaginal or rectal probes, with the intent to strengthen the pelvic floor muscles by innervating the bladder and urethra (Falland Lindstrom 1991). For the purpose of this Assessment, the following definition of pelvic floor electrical stimulation (PFES) treatment will be used: the use of a non-implantable electrical device that delivers variable rates of current through the pelvic floor with the intent of strengthening pelvic floor musculature.

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The device used in PFES generally includes an internal probe that delivers the electrical current and an external device for controlling the electrical stimulation. The intent of PFES is to innervate the pudendal nerve in order to improve urethral closure by activating the pelvic-floor musculature. PFES is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. PFES is also intended to exercise and strengthen the pelvic floor muscles. The methods of PFES have varied in location (vaginal, rectal), stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration, pulse-to-rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings (Fantl et al. 1996). Variation in the amplitude and frequency of electrical pulse is used to mimic and stimulate the different physiologic mechanisms of the voiding response (Fall and Lindstrom 1991). For urge incontinence, the objective is to reinforce the inhibitory system; these inhibitory neurons operate at low frequencies, so stimulation is generally administered at 5-20 Hz. For stress incontinence, the objective is to activate the motor neurons, so stimulation is generally administered at 20-50 Hz. For mixed incontinence, the treatment sessions generally alternate between those for urge and stress incontinence.

Contraindications for PFES include diminished sensory perception, pregnancy or plans to become pregnant, urinary retention, polyuria greater than 4 liters per day, recurrent vaginal infections, vaginal lesions or tumors, atrophic vaginitis, vesico-vaginal fistula, prolapsed uterus, anal fissure, recurrent or present urinary tract infection, implanted pelvic device, cardiac pacemaker, cardiac arrhythmia or defibrillator, abnormal neurologic findings, and menstrual abnormalities (Gallo and Sasso 1997; Siegel et al. 1997; Sand et al. 1995; Brubaker et al. 1997). Additional exclusion criteria typically include inability to comprehend directions for safe PFES home use, less than one leakage episode recorded over a 3-day period, pelvic surgery in past 6 months, pelvic irradiation, current incontinence treatment or use of drugs that may affect urinary incontinence, and age less than 18 years. FDA Status. Since 1991, the Food and Drug Administration has cleared several brands of pelvic floor electrical stimulators for commercial use under

section 510(k) of the Federal Food, Drug, and Cosmetic Act.

#### Prior evidence-based review

A systematic review of the efficacy of PFES was performed by Berghmans et al. (1998). These authors used a comprehensive search strategy with multiple databases to identify all the published literature on this topic between 1980 and 1998 published in English, German, or Dutch. Their criteria for inclusion were: 1) randomized, controlled trial, 2) reported results exclusively or separately on women with stress incontinence, 3) the intervention or reference group consisted of PME with or without other interventions, 4) the outcome measures were clinically relevant and reliable for the problem. Their analysis included a formal assessment of methodologic quality, with division of studies into the categories of "sufficient quality" or of "low quality."

Six trials were identified that compared PFES to sham PFES, four of which were included in the current Assessment (Sand et al. 1995; Luber and WoldeTsadik 1997; Laycock and Jerwood 1993; Blowman et al. 1991). Of the other two trials reviewed by Berghmans et al., one did not meet the inclusion criteria for the current review due to a lack of correct outcome measures (Shepherd et al. 1984) and the final trial was published in German (Hofbauer et al. 1990). Four of the 6 trials reported a benefit for PFES over placebo, two of which were judged to be of "sufficient methodologic quality" (Sand et al. 1995; Blowman et al. 1991). The authors concluded that there was strong evidence for the efficacy of PFES versus sham PFES. They added that these results must be viewed with caution due to the lack of consistency between trials in the type of stimulation and the stimulation parameters used.

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Five trials were identified by Berghmans et al. (1998) that compared PFES with an alternative behavioral intervention (PME - 3 studies; vaginal cones 2 studies; PME plus cones - one study), four of which were included in the current Assessment (Olah et al. 1990; Hahn et al. 1991; Laycock and Jerwood 1993; Smith 1996). The fifth trial was published in German (Hofbauer et al. 1990). Only one of these trials was judged to be of sufficient methodologic quality by the authors (Olah et al. 1990). In none of these trials was PFES superior to any of the behavioral interventions. The authors concluded that there was limited evidence that there is no difference between PFES and other types of behavioral interventions.

#### **Methodologic Considerations**

The available literature evidence consists of numerous clinical series of PFES treatment, and a small number of controlled trials. Early studies of electrical stimulation were case reports demonstrating positive treatment for urinary incontinence. Clinical studies performed since the mid-1980s have suggested that pelvic floor electrical stimulation improves stress, urge, or mixed incontinence. The literature reports a decrease in incontinence episodes ranging from 10% to 75%, percent cure from 8% to 52% and percent improvement from 38% to 94% (Kralj and Lukanovic 1988; Bent et al. 1993;

Zollner-Nielson and Samuelsson 1992; Dumoulin et al. 1995; Siegel et al. 1997; Caputo et al. 1993; Plevnik et al. 1986; Sand 1996; Ericksen and EikNes 1989; Ericksen et al. 1989; Richardson et al. 1996).

Evidence reported from such single-armed clinical studies tends to overestimate treatment effect (Sacks et al. 1983; Colditz et al. 1989). The pretest-posttest design (the "before-after" study), often employed in clinical series, is the comparison of observations at baseline to observations that occur after an intervention. A major limitation in this type of study design is that rival sources of explanation for changes in outcomes are numerous and uncontrolled. For example, before-after studies do not account for placebo effects, the natural history of the disorder being studied, or other modifying factors that may have an effect on outcomes. For incontinence, there are numerous factors that may impact on the outcomes that are measured, such as education, medication use, activity level, and expectations for treatment. In a trial without concurrent controls, it is impossible to ascertain how much of the improvement seen is due to these types of factors, as opposed to the effect of the intervention.

Campbell and Stanley published a classic handbook on research methodology that still provides a solid framework for evaluating the validity and generalizability of scientific evidence (Campbell and Stanley 1966). The Campbell and Stanley framework classifies clinical series research design as pre-experimental. All the pre-experimental designs are weak forms of scientific research design because they are subject to extraneous factors that provide alternative explanations of the results. When alternative explanations are present, an experiment is ambiguous because the extraneous factors interfere with the conclusion or inferences to be drawn. While clinical series often provide descriptive information and the historical interest in framing a research question, the lack of internal validity excludes studies using a clinical series design as scientific evidence (Guyatt et al. 1994; Sackett 1979; Feinstein 1985; Campbell and Stanley 1966). Clinical series may also provide some information on the durability of a treatment *effect*, given that efficacy has been established in well-designed, controlled trials of shorter duration. Expert panels in reviewing scientific evidence have ranked the quality of this type of evidence in the lowest category of rigor (Fantl et al. 1996).

In addition there are several concerns specific to the evaluation of efficacy in incontinence. The measurement of the frequency of incontinence is limited both by inherent variability in the condition itself, and by potential inaccuracies in the available measurement instruments. For patients with stress incontinence, the specific activities performed during a given time period will impact on the frequency of incontinence. Day to day variability in activities may be associated with variability in frequency of incontinence. Other variables, such as fluid or caffeine intake, may also contribute to underlying variability in the condition.

Also, the measurement instruments available to quantitate outcomes of incontinence are not ideal (Fantl et al. 1996). Patient recorded diaries have a fair amount of subjectivity. Adequacy of documentation may introduce an additional level of variability to the data. The pad test, while perhaps more objective than patient reported diaries, may be less

useful clinically since the maneuvers performed during this test may or may not correspond to the usual types of activities performed by patients. The precision and reproducibility of the pad test is not well reported in the literature.

As with most medical interventions, there is expected to be some degree of placebo response in clinical trials of treatment for incontinence. For example, in a recent well-designed trial comparing PME to drugs (Burgio et al. 1998), a placebo "drug" group was included. This placebo group had a 39.4% improvement in the frequency of incontinence by patient reported diary. The majority of studies of PFES versus "sham" PFES report a substantial placebo effect, ranging up to 28% improvement in the frequency of incontinence.

Because of the above methodologic considerations, clinical trials with concurrent controls are needed to demonstrate the efficacy of PFES. Randomized controlled trials with adequate numbers of patients are the ideal types of studies that minimize bias and confounding. Controlled trials that are nonrandomized, while prone to selection bias, may also provide sufficient evidence of efficacy if the comparability of the treatment arms can be adequately assessed. Trials without concurrent controls, however, have too great a potential for bias to allow conclusions on the relevant assessment questions. Thus, this Assessment will be restricted to controlled trials, either randomized or non-randomized, involving PFES as a treatment for urinary incontinence.

## **METHODS**

### **Search Methods**

The MEDLINE database was searched for the periods of 1966 through January 2000, using the medical subject heading (MeSH) term "electrical stimulation therapy" and the term "urinary incontinence." A search was also performed using the textwords "pelvic floor electrical stimulation," linked with "urinary incontinence." This search was limited to English language articles reporting on human subjects. All articles describing comparative studies were retrieved. *Current Contents* and bibliographies of recent review articles and clinical trials also were reviewed.

### **Study Selection**

Selection criteria for inclusion in the Assessment included the following:

1. full-length, peer-reviewed articles reporting on outcomes of treatment for urinary incontinence using PFES;
2. included patients with documented stress, urge, or mixed incontinence (by physician diagnosis and/or urodynamic testing), and the methods used for diagnosis are adequately described;
3. included a concurrent comparison group of-patients treated without PFES, in one of the following categories:
  - Placebo-control treatment (e.g., sham PFES or other intended "placebo")



- Treatment with alternative non-surgical therapy for incontinence (PME, vaginal cones, bladder training, pharmacologic agents);
4. included valid health outcome measures (percent decrease in incontinent episodes by patient diary, percent decrease in volume of urine loss on pad test, percent of patients with 50% or greater improvement, percent of patients dry);
  5. adequate description of the patient population, including diagnostic categories of incontinence;
  6. adequate description of the treatment course, including length of treatment, number of sessions, etc.

## **FORMULATION OF THE ASSESSMENT**

### **Patient Indications**

Adults with self-reported involuntary loss of urine, with an objective diagnosis of stress urinary incontinence, urge incontinence, or mixed incontinence. Patients must be cognitively intact, and sufficiently motivated to expect that they will learn and practice PME or comply with the PFES treatment protocol. Patients with neurologic causes of incontinence are not included in this patient population.

### **Technologies to Be Compared**

PFES will be compared to 1) placebo (i.e., treatment with a sham device) and/or 2) alternative non-surgical treatment (e.g., pelvic floor exercises or vaginal cones). In this regard, the focus of this assessment will be to determine whether PFES is an efficacious treatment for incontinence, and whether PFES is equivalent to or better than alternative non-surgical techniques for treatment of urinary incontinence. In addition, PFES used in conjunction with PME will be compared to PME alone, to determine whether PFES confers additional benefit in the treatment of urinary incontinence above PME alone.

### **Health Outcomes**

The main outcome measure used in studies of incontinence is the change in the number of incontinent episodes, usually measured as episodes per week. Study patients keep voiding diaries that include recording the episodes of voiding and urinary incontinence, number of pads used per day, nocturnal voids and urgency episodes without incontinence. The percent change in number of incontinent episodes is calculated using the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

This outcome measure, *percent change* in the frequency of incontinent episodes is the most consistently reported outcome and will be the main outcome measure used for comparing results across studies. Derived from change in the number of incontinent episodes are percent cure and/or percent of patients who improve. Patients who become dry (i.e., no longer experience incontinence following treatment) are considered cure of

incontinence. The proportion of patients with 100% reduction in incontinence is the *percent cure* reported in a study. A reduction of leakage episodes by 50% has been defined by the International Continence Society as a clinically significant improvement (Blaivas et al. 1997). The proportion of patients with 50% or greater reduction in incontinent episodes is the percent of patients with improvement reported in a study.

A standardized pad test may also be used as a valid measurement of the severity of incontinence for patients with stress incontinence. This test measures urine loss during maneuvers expected to induce urinary incontinence. Percent change on the pad test can be calculated in a manner similar to frequency of incontinence, as follows:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$

The parameters of percent cure and percent of patients with improvement for this outcome are calculated in the same manner as with the diary measures.

In addition to these health outcomes, clinical examinations often include measuring perineal muscle strength and/or urodynamic testing. These types of intermediate outcomes do not represent true health outcomes of interest and, thus, will not be considered primary to this Assessment.

Subjective assessments include symptom scales and the Incontinence Impact Questionnaire (Shumaker et al. 1994). These types of patient reported outcomes have not been commonly used in studies to date and, thus, also will not be considered primary to this Assessment.

**Adverse outcomes.** Adverse outcomes occur as a result of electrical stimulation, however these are minor events and are not well-reported in the literature. Potential adverse outcomes of treatment include patient inconvenience, discomfort from the instrumentation, and/or increased anxiety/distress caused by the treatment. Rates of unpleasant side effects (pain, cramping, diarrhea) have been reported at 4% (Siegel et al. 1997), 19% (Sand 1996), 18% (Ericksen et al. 1989) and 7% (Bent et al. 1993). These do not lead to serious morbidity and disappear immediately upon discontinuation of treatment. However, discomfort is one of the reasons for discontinuation of treatment and contributes to the drop out rate of a study.

### **Specific Assessment Questions**

The following questions will be addressed for each of three indications:

- stress incontinence;
- urge incontinence;
- post-prostatectomy incontinence

1. Compared to placebo, is treatment with PFES efficacious in reducing incontinence?
2. What is the efficacy of PFES as compared to pelvic floor muscle exercises or alternative non-surgical treatments?
3. Does the addition of PFES to PME result in improved outcomes above that obtained with PME alone?

## **REVIEW OF EVIDENCE**

Twelve controlled trials met the study selection criteria for this Assessment, reported in 11 published articles. These controlled trials form the primary basis of evidence in determining the efficacy of PFES. One published article contained two distinct studies on different populations (Laycock and Jerwood 1993). The largest trial, by Brubaker et al. (1997), enrolled 146 women, 60 with stress incontinence, 53 with urge incontinence, and 33 with mixed incontinence. However reported outcomes in the Brubaker et al. trial are largely limited to urodynamic testing. Extensive missing values in patient recorded diaries precluded analysis of the intended primary end point, reduction in the frequency of incontinence. One additional controlled trial conducted by Richardson et al. (1996), which compared PFES used daily to PFES used every other day did not meet the study selection criteria for this review because there was no concurrent control group treated without PFES. This study found no difference between the two PFES treatment groups.

### **Stress Incontinence: Placebo-Controlled Trials**

Five trials compared PFES to placebo in a total of 243 patients. All used a sham device that does not transmit electrical impulses (Tables 1a and 1b). Three of these trials (Sand et al. 1995, Luber and Wolde-Tsadik 1997, Brubaker et al. 1997) were randomized and double-blinded; one trial was randomized and single blinded (Laycock and Jerwood 1993); the fifth trial (Yamanishi et al. 1997) was double-blinded but does not appear to be randomized. The number of patients with stress incontinence enrolled in each study ranged from 30-67.

**Sand et al.** Sand et al. (1995) compared outcomes of 35 women receiving PFES treatment and 17 women receiving sham treatment. There were 7 dropouts in the PFES group and one in the placebo group. Three women left the study because they could not meet the visit schedule, 2 complained of persistent vaginal irritation, 1 withdrew because of urgency after 1 week of treatment and 1 withdrew because of diverticulitis, which was unrelated to the PFES device. The woman in the placebo group who withdrew was unable to keep the visit schedule.

**Table 1a. Controlled trials comparing PFES with placebo treatment for stress incontinence - methodologic features**

Mean age 53.2 ± 11.4 years.

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Sand et al. 1995	52 women with urodynamically proven SI by ICS criteria at six clinical sites.	Double- blinded trial. Random assignment to PFES or placebo groups on 2:1 basis. Central randomization site used with list of computer generated numbers.	<b>PFES</b> (Innova, Empi Inc) (n=35) Pts instructed to gradually increase the power to 60-80mA or highest tolerated level  <b>Sham device</b> (n=17)  Each group instructed to use device twice daily for 15-30 minutes. Seven office visits and weekly telephone calls for all patients over a 15-week period.	PFES – 7/35 (20%)  Sham – 1/17 (6%)	Primary outcomes - pt recorded weekly incontinence diary; pt reported 24-hour incontinence diary; quality of life SF-36,	Potential for selection bias Potential for attrition bias(? If analysis was intent-to-treat). PFES group was 80% compliant with protocol and device group 89% compliant.
Luber 1997	67 women with SI by ISC criteria, who had failed or declined PME were offered enrollment, 54 accepted. Average age was 53.9 years.	Double-blind trial. Pts randomized to PFES or sham by opaque envelopes.	<b>PFES</b> (n=26, Hollister, Evanston, Ill)  Frequency 50mHz, power ranged from 10-100mA  <b>Sham device</b> (n=28)  Both groups used device for 15 minutes twice daily for 12 weeks.	<b>PFES</b> 6/26 (23%) Sham 4/28 (14%)	Pts recorded diaries prior to treatment and at the end of treatment period.	

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Laycock 1993	30 women with uro-dynamically documented S1,  Mean age 44.8 years	Single blind trial. Random assignment to PFES or sham PFES. Randomization using random numbers and sealed envelopes.	<b>PFES</b> (Endomed 433) (n=15). Treatment sessions 15-30min at maximum tolerated intensity. Three different frequencies, 1Hz, 10-40Hz, and 40HZ for 10 min each. Completed 'on average' ten treatment sessions. No home use of PFES. <b>Sham device</b> (n=11) Individual instruction in PME and used of vaginal cones was restricted to after the trial. Completed 'up to' ten sham sessions.	PFES – 0/15 (0%)  Sham - 4/15 (27%)	Standardized pad test pre- and post-treatment. Pt recorded diaries completed for one week before treatment and one week after final treatment.	Potential for performance bias. Potential for attrition bias.
Brubaker et al., 1997	60 women with SI, 33 women with MI from four clinical centers.  Mean age 57.7 ± 12.4 yrs (sham group), 56.0 ± 11.9 (PFES group).	Double blind trial. Randomized to PFES or sham PFES stratified by diagnosis. Randomization process not described.	<b>PFES</b> (n=61, Microgyn II, InCare)  Frequency 20HZ, maximum tolerated power  <b>Sham device</b> (n=60)  Use of assigned device at home, 20 minutes twice per day for 8 weeks	PFES – 11/72 (14%)  Sham 16/76 (21%)	Pt recorded diary, completed at four time points during the study.  Incontinence-specific quality of life instrument	81% compliance with treatment regimen Excessive missing data precluded analyses on diary (number of episodes, leakage, pads used)
Yamanishi et al. 1997	35 Japanese patients with SI (n=31) and MI (n=4), including 5 men and 30 women. Average age 63 ± 13 years	Double-blind trial. Group allocation process not reported.	<b>PFES</b> (n=4 male & 16 female) Frequency 50Hz, power 60mA.  >Sham device (n= 1 male & 12 female) Both groups used device at home for 15 minutes two or three times daily for 4 weeks	PFES 1/20 (5%)  Sham 1/13 (8%)	Pt recorded diaries (frequency not specified)  Standardized pad test	Pt population not well-described  Potential for selection bias

**Table 1b. Controlled trials comparing PFES with placebo treatment for stress incontinence – outcomes**

Study/year	Patient/ Groups	PT recorded diaries  % % pts Measure Pre- Post- change1 improv2 improv2, %cure3	Pad test (grams)  %%pts% Measure Pre- Post- change1 improv2 improv2 °/ocure3	Comments
Sand et al. 1995	PFES (n=28)  Sham (n=16)  PFES (n=28)  Sham (n=16)	Leaks/wk 14.2 10.0 30%* NR NR  Leaks/wk 20.1 27.0 -34% NR NR  *p=0.009 as compared to sham group  Leaks/day 3.1 1.8 42% 37% **0%  Leaks/day 3.0 3.8 -26% 12% 6%  *p=0.04 as compared to sham group  **p=0.05 as compared to sham group  No significant differences between groups on cure rates	45.2 15.4 65.9%* 46% 20%  30.0 32.3 -8% 18% 12%  * p=0.005 as compared sham group  ** p=0.05 as compared to sham group  No significant differences between groups on  cure rates	p-values are from one- tailed (directional) hypothesis tests. – No significant differences Between groups on quality of life measures by SF-36
Luber 1997	PFES (n=26)  Sham (n=11)	Leaks/day 2.8 2.4 14% NR 10%  Leaks/day 2.7 2.4 11% NR 17%  No significant difference in improvement between groups on any outcome measure	-- -- -- -- --  -- -- -- -- --	

Study/year	Patient/ Groups	PT recorded diaries  % % pts Measure Pre- Post- change1 improv2 improv2, %cure3	Pad test (grams)  %%pts% Measure Pre- Post- change1 improv2 improv2 °/ocure3	Comments
Laycock 1993	PFES (n=15)  Sham (n=11)	<p>--- -- NR (13.3%)</p> <p>--- -- NR (0%)</p> <p>No significant difference in frequency of leaks between Groups (details NR) or in % cure rates between groups</p>	<p>NR NR 66.3% * NR NR</p> <p>NR NR 27.7% NR NR</p> <p>*p=0.0085 as compared to sham group</p> <p>** p=0.01 as compared to sham group</p> <p>*** Percent cure defined as no reported leakage</p> <p>on pt diary and &lt;1.0 gms leakage on pad test Difference between groups NS</p>	
Brubaker et al., 1997	PFES (n=61)  Sham (n=60)	<p>Leaks/day NR 2.2 NR NR NR</p> <p>Leaks/day NR 2.4 NR NR NR</p> <p>No significant difference between groups on post - leaks/day</p>	<p>-----</p> <p>-----</p>	Excessive missing data precluded primary analyses on diary measures.

Study/year	Patient/ Groups	PT recorded diaries	Pad test (grams)	Comments
Yamanishi 1997	PFES (n=20)  Sham (n=13)	Leaks/day 6 4 33%* 80%** (50%)***  Leaks/day 5.8 5.8 0% 18% (8.3%)  *p=0.047 as compared to sham group  ** p=0.02 as compared to sham group  *** Percent cure defined as no reported leakage on pt diary and <1.0 gms leakage on pad test p=0.03 as compared to sham group	25 9 56%* 93%** (50%)***  11 16 -45% 27% (8.3%)  p=0.008 as compared to sham group  p=0.01 as compared to sham group  p=0.01 as compared to sham group  *** Percent cure defined as no reported leakage on pt diary and <1.0 gms leakage on pad test p=0.03 as compared to sham group	No patientcomplai ned of adverse events.

1 % change - Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

2 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

3 % cure - Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e., no incontinent episodes over the specified time period.

4 % change - Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$



pretreatment pad weight difference

5 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

6 % cure - Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

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**Key to Tables**

ICS International Continence Society

MI Mixed incontinence (stress and urge incontinence)

%change Percent change in incontinence (frequency by pt recorded diary or urine loss on pad test)

%cure Percent of patients with no further incontinence

% pts improv Percent of patients with >50% decrease in incontinence (frequency by pt recorded diary or urine loss on pad test)

PFES Pelvic floor electrical stimulation

PME Pelvic floor muscle exercise

SI Stress incontinence

UI Urge incontinence

Selection bias Imbalances in patient characteristics between groups with potential for differences to affect outcomes

Performance bias Inequality in the intensity of treatment given between groups

Attrition bias Significant number of dropouts in one or more study arms, not taken into account in the statistical analysis

PFES treatment consisted of a transvaginal stimulation device. Patients were instructed to gradually increase the amperage to 60-80 mA or the highest tolerable level. The device provided stimulation simultaneously at 12.5 Hz and 50 Hz frequencies. Treatment sessions were 15 minutes twice daily for the first 4 weeks and 30 minutes twice daily for weeks 5 through 12. Sixty-one percent of the PFES patients used their device for more than 50 hours of the 70 hours of expected treatment (80% compliance).

After 12 weeks of home treatment, the PFES group decreased the mean number of leaks per week from 14.2 to 10.0; which was a 30% improvement over baseline ( $p=0.03$ ). However, the sham group increased their leaks per week from 20.1 to 27.0, which was 34% worse than baseline ( $p=0.10$ ). The difference between PFES and sham treatment was highly significant ( $p=0.009$ ), although it did not appear that this analysis was by intent-to-treat. An intent-to-treat analysis was reported for patients improved by at least 50% from baseline or cured. On the pad test, the proportion of persons with at least 50% improvement was 46% for PFES and 18% for sham treatment ( $p=0.05$ ); the percent of patients cured was 20% for PFES and 12% for sham treatment ( $p=0.38$ ). Voiding diaries showed at least 50% improvement in frequency of incontinence for 37% of the PFES patients and 12% of the sham-treated patients ( $p=0.05$ ); cure rates by patient reported diary were 0% for PFES and 6% for sham-treatment ( $p=0.33$ ).

The PFES treated group showed statistically significant improvement compared to the control group on visual-analog scores of urinary incontinence, stress incontinence, and frequency of urine loss. There was no significant difference in quality of life scores on the SF-36 Health Survey.

Despite randomization, the two treatment groups may have differed at baseline. The sham group was statistically significantly older than the PFES group (57.7 +/- 13.3 years vs. 50.9 +/- 9.8 years,  $p=0.04$ ). The sham group also had more baseline leakage episodes per week than the PFES group (20.1 vs. 14.2), although a statistical test reported no significant difference in leakages at baseline across groups ( $p=0.91$ ). The comparison of group differences is influenced by an unexplained increase in leakages reported by the sham treatment group (20.1 to 27.0 episodes per week,  $p=0.10$ ) which may lead to overestimation of both the effect of PFES and the statistical significance of the difference between treatment groups. The dropout rate was also higher in the PFES group than the placebo group (20% vs. 6%). For the change in frequency of incontinence, it does not appear that the analysis was done on an intent-to-treat basis. The pre-treatment baseline values for frequency of incontinence differ slightly from the baseline values for the entire

population, implying that some patients have been excluded from analysis. Thus, while this trial reports a statistically significant reduction in incontinence with PFES, there is potential for selection bias and attrition bias, as well as an unusual worsening of outcomes in the placebo group.

Although the trend toward an increase in leakages over baseline reported in the placebo group did not reach significance ( $p=0.10$ ), it is likely that this group was too small ( $n=17$ ) to detect a statistically significant change from baseline. This worsening of incontinence in the control group might influence the interpretation of the results. It is not biologically plausible that the severity of urinary incontinence would progress to this degree over a 12-week period. A more likely explanation is that this worsening results from instability in the measurements of incontinence. This instability may be partly due to inherent fluctuations that individuals experience in the frequency of incontinent episodes. Also, the number of leakages is based on patient-recorded diaries, and additional variability may be introduced by errors in recall and inconsistency in recording incontinent episodes.

Data from the Sand et al. (1995) trial suggests that variability measurements is considerable and greater in the sham group as compared to the PFES group. There was greater within-group variance in leakages per week in the sham group as compared to the PFES group, both at baseline ( $20.1 \pm 8.83$  SE vs.  $14.2 \pm 2.78$  SE) and post-treatment ( $10.0 \pm 2.45$  SE vs.  $27.0 \pm 13.06$  SE). Sand et al. (1995) reported only the standard error of the mean for these measures, although the standard deviation is generally considered a more informative measure of variance (Hopkins 1997). Using the formula  $SEM=SD/(\text{square root of sample size})$ , we calculated the mean and standard deviations of the sham vs. PFES groups as follows: baseline ( $20.1 \pm 36$  vs.  $14.2 \pm 16.45$ ); post-treatment ( $27.0 \pm 53.8$  vs.  $10.0 \pm 14.5$ ).

**Luber et al.** Luber et al. (1997) conducted a randomized double-blind, placebo-controlled trial of 44 women with stress incontinence who had either failed or declined treatment with PME. In the PFES group, 26 women were enrolled but 3 women dropped due to discomfort, 2 women dropped out due to discouragement and 1 woman died from reasons unrelated to treatment. In the placebo group, 28 women enrolled and 4 dropped out, 2 women dropped due to discomfort with the sham device and 2 women because of discouragement.

The vaginal electrical stimulation comprised two 15-minute treatment sessions per day over a course of 12-weeks of home treatment. The pulse was 2 seconds of stimulation followed by 4 seconds of rest. The frequency was 50 Hz and the power ranged from 10-100 mA.

Women completed a 24-hour voiding diary at the start and end of treatment. The PFES group averaged 2.8 (range 1-9) episodes per 24-hours at baseline and 2.4 (range 0-9) episodes at post-treatment. The placebo group averaged 2.7 (range 1-12) episodes per 24 hours at baseline and 2.4 (range 0-11) episodes post-treatment. The results were not

statistically significant either between groups or from baseline to post-treatment within groups.

Women were asked post-treatment if they had a complete resolution of stress incontinence. There was no difference between groups (10% and 16.7% for PFES and placebo, respectively). There also was no difference in cure rates as measured by a stress test on urodynamics with a full bladder, 15% and 12.5% for PFES and placebo, respectively.

This trial is of interest because it was the only trial that restricted eligibility to women who had failed or refused PME. It has been suggested that PFES might be of greater benefit to the subgroup of patients that has failed to improve with PME. Of all women enrolled, 69% of the PFES group and 57% of the placebo group had previously failed PME. The results of the Luber trial do not demonstrate benefit in the subgroup of women who have failed PME.

**Laycock and Jerwood.** Laycock and Jerwood (1993) enrolled 30 women with documented stress incontinence in a randomized, single blind trial. There were four dropouts in the placebo group (27%) and none in the PFES group. PFES sessions occurred in the clinic, with the PFES group receiving "on average" 10 sessions, and the placebo group receiving "up to" ten sessions. Outcomes reported were percent decrease in grams of urine on a standardized pad test and percent cure. Cure was defined as no reported leakage on patient reported diary and less than 1.0 grams of leakage on the pad test. The results of this trial may be affected by attrition bias, and it is also possible that performance bias was present.

Patients in the PFES group showed a significantly greater decrease in grams of urine leaked on the pad test compared to the placebo group (66.3% vS. 27.7%,  $p=0.0085$ ). Percent of patients cured was not statistically significant (13% PFES vS. 0% sham). Percent of patients with greater than 50% improvement was not reported.

**Brubaker et al.** The largest randomized clinical trial (Brubaker et al. 1997) compared PFES with sham treatment in 146 women with stress incontinence ( $n=60$ ), detrusor instability ( $n=28$ ), or mixed incontinence ( $n=33$ ). The results for patients with detrusor instability are reviewed in the section on urge incontinence. There were 27 (18%) dropouts over the 8 week trial; 14% in the PFES arm and 21% in the sham arm (not significantly different).

PFES was transvaginal electrical stimulation at 20 Hz administered in a 2-second work and 4-second rest cycle. Patients were instructed to stimulate at the maximum tolerable level for 20 minutes, twice daily. The duration of treatment was 8 weeks of home therapy. All women received the same treatment, regardless of stress incontinence or urge incontinence diagnosis. This stimulation frequency is in the upper ranged generally administered for urge incontinence (5-20 Hz) and the lower range generally administered for stress incontinence (20-50 HZ).

The results of this trial are largely limited to comparison of pre- and post-treatment urodynamic testing. Outcomes of primary interest to this assessment, improvement and cure as measured by voiding diaries or pad testing were not reported. Brubaker et al. were unable to analyze patient-reported diaries due to excessive missing entries. In an attempt to overcome the noncompliance with voiding diaries, the number of accidents per 24 hours were obtained as 6-week follow-up data. There was no difference between PFES and sham treatment groups at 6 weeks post treatment ( $p=0.75$ ), but baseline values are not available to assess change. There was no significant difference between the PFES and sham groups in pre-and post-intervention change in stress incontinence, as measured by urodynamic testing.

However, pre- and post-treatment urodynamic evaluation showed significant improvement in patients who had detrusor instability. It has been proposed this finding suggests that the stimulation frequency in the Brubaker study was too low to effectively treat stress incontinence (Stuart and Elixhauser 1998). Delineation of optimal parameters for pelvic floor electrical stimulation is a matter for empirical investigation. Brubaker et al. state that their study was not adequately powered to demonstrate lack of efficacy for stress incontinence. Nor can Brubaker et al's findings on detrusor instability support an inference that PFES at higher stimulation frequency is effective in the treatment of stress incontinence.

**Yamanishi et al.** Yamanishi et al. (1997) conducted a double-blind controlled trial in 30 women with stress incontinence and 5 men, 4 with urge incontinence and 1 stress incontinence. This study was probably not randomized, as there is no statement that the trial was randomized, nor was the group allocation process reported.

The PFES group consisted of 16 women and 4 men, and the sham device group consisted of 12 women and 1 man. An anal device was used in men and a vaginal device in women. Two women, one in each group, dropped out due to discomfort with the device. Electrical pulses were 50 Hz with maximum amperage of 60 mA. Patients were instructed to deliver maximum tolerable stimulation for 15 minutes 2 or 3 times daily for 4 weeks.

Baseline and outcome data was estimated from graphs in the published article by Yamanishi et al. and thus is approximate. The baseline number of episodes of leakages per day was 6 in the PFES group and decreased to 4 per day after 4 weeks of treatment (33% improvement,  $p=0.004$ ). In the sham group, the baseline number of leaks per day was 5.8 and remained unchanged following placebo treatment. The difference between the two groups on change in episodes of leakage was statistically significant ( $p=0.047$ ).

Results for women alone were reported on percent cure and percent improvement. Cure was defined as no reported leakage on patient diary and less than 1.0 grams of leakage on the pad test. The percent cure was 50% for PFES and 8.3% for sham treatment ( $p=0.024$ ). The percent of patients with at least 50% improvement, 'as' measured by patient diaries, was 80% in the PFES group and 18% in the sham group ( $p=0.02$ ). On the pad test, the percent of patients improving at least 50% was 93% in the PFES group and 27% in the sham group ( $p=0.01$ ).

**Summary.** Five trials compared PFES to sham treatment in patients with stress incontinence. The total number of patients studied is small relative to the population with stress incontinence. These trials do not provide strong and consistent evidence that PFES reduces the frequency and severity of incontinent episodes compared to placebo.

Statistically significant results favoring PFES were reported in three trials. The trial by Sand (1995) et al, although randomized and double-blinded, may be influenced by a high degree of variability in incontinent episodes in the control group, which consisted of 17 patients. The trial by Yamanishi et al. (1997) enrolled 30 women reported high rates of improvement and cure in the PFES group. Although double-blinded, this trial does not appear to be randomized. The single-blind randomized trial by Laycock and Jerwood (1993), which enrolled 30 women, found a significant percent reduction in grams of urine leaked in the PFES group compared to placebo. This trial was potentially prone to performance bias and attrition bias.

The largest of the five trials comparing PFES to sham treatment enrolled 60 women with stress incontinence and 33 with mixed incontinence (Brubaker et al. 1997). Due to excessive missing data in voiding diaries, the results of this trial are largely limited to comparison of pre-and post-treatment urodynamic testing. There was no significant difference in changes in stress incontinence in the PFES group compared to sham treatment. In the fifth trial, Luber et al. (1997) found no difference between PFES and sham treatment in a trial of 44 women who had failed or declined treatment with pelvic muscle exercises.

### **Stress Incontinence: PFES compared to alternative conservative treatments**

Five controlled trials compared PFES to PME or other nonsurgical alternatives (Table 2a and 2b). All five trials were randomized, one was single-blinded (Bo et al. 1999), and the others did not report any blinding. A total of 260 patients were enrolled in these trials, with study sizes ranging from 18-107. The largest trial had 4 arms; PFES, PME, vaginal cones, and no treatment (Bo et al. 1999). Of the four 2-arm trials, 3 compared PFES to PME (Smith 1996, Laycock and Jerwood 1993, Hahn et al. 1991), and the fourth compared PFES to vaginal cones (Olah et al. 1990).

**Bo et al.** Bo et al. (1999) randomized 107 patients from five clinical centers to four groups: PFES, PME, vaginal cones, and waiting-list control. PFES was used at home once daily for 30 minutes at the maximally tolerated intensity.

The PME treatment used in this trial was a structured program, including a 45-minute group exercise session each week led by a physical therapist. Participants were also instructed to practice their exercises 3 times/day and an audiotape was available for home training. Prior studies had shown this structured PME program to be more effective than home exercises.

Dropouts were higher in the PFES (22%) and PME (14%) groups, and somewhat lower in the vaginal cone (7%) and control (6%) groups. The primary analysis was by

treatment-received. The authors also reported that an intent-to-treat analysis gave virtually identical results, except results were slightly weaker for the PFES group.

All three treatment groups showed efficacy on some outcome measures compared to the control group, but improvement in incontinence was consistently larger for the PME group across all outcome measures. On the pad test, PME was superior to PFES on percent change in grams of urine leaked (78.2% vs. 13.2% (p=0.02). There were no reported significant differences in other outcome measures between PME and PFES.

The effectiveness of PME in treatment of stress incontinence reported by the Bo et al. study is likely to be generalizable to the Medicare population. Although the mean age of the PME arm was 49.6 (+/- 10.0) years, somewhat younger than the Medicare population, the effectiveness of PME in a population closer to Medicare age has been previously reported in a randomized controlled trial (Burns et al. 1993). The participants in this study were over age 55 years, cognitively intact, middle-class, community-dwelling women. The mean age of participants was 63 (+/- 6) years; 34% of participants were age 65 and older.

**Table 2a. Controlled trials comparing PFES with alternative non-surgical treatments for stress incontinence - methodologic features**

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Bo 1999	<p>107 women with urodynamically documented SI, on surgical waiting list or recruited from newspaper ads from five clinical centers in Norway.</p> <p>Mean age 47.2 ± 10.1 years (PFES), 49.6 ± 10.0 years (PME), 49.2 ± 10.6 years (cones), 51.7 ± 8.8 years (control)</p>	<p>Single blind trial.</p> <p>Randomization by computer generated numbers and opaque envelopes, stratified by frequency of incontinence.</p> <p>Physicians performing outcome assessment blinded to group allocation</p>	<p>Length of treatment -6 months</p> <p>PFES (n=32, Vitacon AS, MS 106 tWin) 30min once/day at frequency 50Hz, maximum tolerated intensity.</p> <p>PME (n=29), 45 min sessions weekly with therapist, home practice three times/day</p> <p>Vaginal cones (n=29). 20min/day with progressive increase in weight of cones &gt;Control(n=32)</p> <p>Pts in all four groups received education on incontinence.</p> <p>Pts in three treatment groups met with therapist once/month</p>	<p>PFES 7/32 (22%)</p> <p>PME 4/29 (14%)</p> <p>Cones 2/29 (7%)</p> <p>Ctrl 2/32 (6%)</p>	<p>Standardized pad test</p> <p>Pt recorded diaries completed for three days before and after the intervention period.</p>	<p>Primary analysis by treatment received. Secondary analysis by intent to treat with 'virtually the same results'.</p>



Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Smith 1996	<p>18 women with urodynamically document SI.</p> <p>Mean age 50.5 years, range 26-72 years</p>	<p>Unblinded (?) trial.</p> <p>Patients randomized to PFES or PME. Randomization process not described.</p>	<p>Length of treatment – 4 months</p> <p><b>PFES</b> (n=9, Stimtech Products), home use 60 minutes twice/day, frequency 12.5Hz and 50HZ simultaneously, gradually increasing intensity to a maximum of 80mA.</p> <p>PME (n=9). Pts given written materials and initial instruction session. Instructed to practice exercises 60 times/day</p>	<p><b>PFES</b> - 0/9 (0%)</p> <p>PME 0/9 (0%)</p>	<p>Pt recorded voiding diaries kept throughout course of study.</p>	<p>Low power to detect treatment differences.</p>
Olah 1990	<p>69 pts with symptoms of SI. Excluded pts treated with PME in last 6 months.</p> <p>Mean age 43.2 ± 8.9 years (cones), 47.9 ± 13 years (PFES)</p>	<p>Unblinded (?) trial</p> <p>Pts randomized to PFES or weighted vaginal cones. Randomization process not described.</p>	<p>Length of treatment – 4 weeks</p> <p>PFES (n=36, device not specified). Treatment in clinic for 15 minutes 3x/week at maximum tolerated intensity between 0 – 100mA.</p> <p>Cones (n=33). Home use 15 minutes twice/day with increasing cone weight. Weekly sessions with therapist. All pts taught PME.</p>	<p>PFES – 6/36 (17%)</p> <p>Cones 9/33 (27%)</p>	<p>Pt recorded voiding diaries completed one week prior to treatment</p> <p>Standardized pad test</p>	<p>Intent – to – treat analysis.</p> <p>Improvement in both groups possibly confounded by concurrent performance of PME's</p>

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Laycock 1993	46 women with uro-dynamically documented SI,  Mean age 40.8 years, range 28-59 years	Unblinded trial. Random assignment to PFES or PME.  Randomization using random tables and sealed envelopes.	Length of treatment – 6 weeks  <b>PFES</b> (n=23). Treatment sessions 15-30 min at maximum tolerated intensity. Three different frequencies, 1Hz, 10-40 Hz, and 40Hz for 10 min each. Completed 'on average' ten treatment sessions. No home use of PFES.  <b>PME</b> (n=23) Completed an average of six treatment sessions and vaginal cone therapy.	PFES – 0/23  (0%)  PME – 6/23  (26%)	Standardized pad test pre- and post – treatment.  Pt recorded diaries completed for one week before treatment and one week after final treatment.	Potential for performance bias.  Potential for attrition bias.
Hahn 1991	20 women with SI referred for surgery.  Mean age 47.2 years, range 34-62 years	Unblinded trial.  Pt randomized to PFES or PME. Randomization process not described.	Length of treatment – 6 months  <b>PFES</b> (n=10) (Contelle). Home use of device for 6-8 hours at night. <b>PME</b> (n=10). Instructed to perform PME 6-8 times/day. Visits with therapist weekly for 4 weeks, then monthly.	PFES - 0/10  (0%)  PME – 0/10  (0%)	Modified version of standardized pad test.	Potential for performance bias.  Low power to detect group differences

**Table 2b. Controlled trials comparing PFES with alternative nonsurgical treatments for stress incontinence – outcomes**

Study/year	Patient/ Groups	PT recorded diaries	Pad test (grams)	Comments
Bo 1999	PFES (n=32)  PME (n=29)  Vaginal cones (n=29)  Control (n=32)	Leaks/3d 2.3 1.6 30.4% NR NR  Leaks/3d 2.0 0.8 60.0% NR NR  Leaks/3d 2.7 1.9 29.6% NR NR  Leaks/3d 2.9 2.6 10.4% NR NR  PME > control (p=0.01)  PFES > control (p=0.02)	% %pts% Measure Pre- Post- change1 improv2 improv2, %cure3  56.0 48.6 13.2% NR 28%  38.6 8.4 78.2% NR 44%  48.4 33.7 30.4% NR 14.8%  51.4 38.7 24.7% NR 6.7%  PME > control (p=0.02) PME > PFES (p=0.02) and PME > cones  (p=0.01)	Compliance with PME > PFES or cones (p<.002)  Adverse effects: PFES – pain 2 pts Difficulty using device  In 8 pts  PME – none  Cones – pain in 1 pt vaginitis in 2 pts  difficulty using device in 14 patients
Smith 1996	PFES (n=9)  PME (n=9) Sham (n=11)	Leaks/day 3.0 1.4 53% 44% 22%  Leaks/day 3.0 2.4 20% 33% 11%  No group differences were statistically significant.	--- --- ---	
Olah 1990	PFES (n=36)  Vaginal cones (n=33)	Leaks/wk 19.3 7.7 60% NR 11.1%  Leaks/wk 22.0 8.2 63% NR 12.1%  No group differences were statistically significant.	32.2 10.5 67% NR NR  27.7 14.0 49% NR NR	Continued improvement at 6mths follow-up with no further treatment

Study/year	Patient/ Groups	PT recorded diaries  % % pts Measure Pre- Post- change1 improv2 improv2, %cure3	Pad test (grams)  %%pts% Measure Pre- Post- change1 improv2 improv2 °/ocure3	Comments
Laycock 1993	PFES (n=23)  PME (n=23)	Statistically significant decrease in the frequency of leakage both groups(details not given). P=0.02807 for PFES, p=0.04318 for PME)  No group differences were statistically significant.	NR NR NR NR 4.3%  NR NR NR NR 17.6%  Group differences not statistically significant.	
Hahn 1991	PFES (n=10)  PME (n=10)	--- ---	57.5 38.1 34% 50% 40%  53.2 20.6 61% 80% 10%  Data estimated from graphical representation  No significant difference between groups reported	

1 % change - Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

2 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

3 % cure - Defined as the percentage of patients with 100% decrease in frequency of incontinence, ie no incontinent episodes over the specified time period.

4 % change - Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

**pretreatment pad weight difference - posttreatment pad weight difference x 100**

pretreatment pad weight difference

5 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

6 % cure - Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

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**Smith.** Smith (1996) compared PFES with PME (Tables 2a and 2b). An intravaginal electrical stimulation device delivered stimulation at both 12.5 Hz and 50 Hz. The amplitude for stress incontinence patients was gradually increased to 80 mA.. Treatment sessions were initially 15 minutes twice a day and were increased to 60 minutes twice a day.

The stress incontinence arm of the randomized controlled trial compared PFES against PME alone. After 4 months of therapy, women who received PFES did not differ from women who engaged in PME in number of accidents per 24hour period, percent cure, or percent improvement. The sample size for each group was only 9 women, thus, the comparison did not have the sensitivity to detect whether the 53% change in leakage for PFES was better than the 20% change for PME.

**Olah et al.** Olah et al. (1990) compared PFES to vaginal weighted cone treatment in women referred to physiotherapy for symptoms of stress incontinence. Women visited

the physical therapy department 3 times weekly for 4 weeks. External inferential stimulation was delivered by placing 2 electrodes on the abdomen and 2 on the inside of the thighs. A current up to 100 Hz was used depending on the maximum tolerable level. Each treatment session was 15 minutes.

All women were instructed in PME as ancillary treatment but compliance was not assessed. An intent-to-treat analysis showed no differences between groups. At 6-month follow-up, the percent change on the pad test improvement for PFES was 70% and for the cones, 90%.

**Laycock and Jerwood.** Laycock and Jerwood (1993) randomized 46 women with documented stress incontinence to PFES or PME. No patients in the PFES group dropped out, while 26% of the patients in the PME group dropped out. PFES was given in the clinic for 15-30 minutes at the maximum tolerated intensity, and patients received an average of ten sessions. Patients in the PME group had an average of six sessions with a therapist and were instructed to practice the exercises every hour while awake. They were also supplied with and instructed on the use of vaginal cones. No group differences were statistically significant.

**Hahn et al.** Hahn et al. (1991) randomized 20 patients to a 6-month trial of PFES or PME. The patients in the PFES group used the device at home for 6-8 hours/night. Patients in the PME group had weekly visits with a therapist for the first month, then monthly visits. They were instructed to practice 6-8 times/day. Data on percent improvement on a standardized pad test was estimated from graphical representation. Results of the pad test showed greater percent reduction in leakage weight on the pad test in the PFES group (61% vs. 34%,  $P < 0.10$ ) but a greater percent cure in the PME group (40% vs. 10%,  $P = 0.30$ ). None of the group comparisons in this small study reached statistical significance.

**Summary.** Five randomized controlled trials, including a total of 260 patients, compared PFES to alternative conservative treatment (PME or vaginal cones) for treatment of stress incontinence. Only one trial reported statistically significant results. This 4-arm, single-blinded trial by Bo et al. (1999), found that a structured PME program ( $n=29$ ) was superior to PFES ( $n=32$ ) on the percent improvement on standardized pad test. In this trial there was a 78.2% decrease in urine loss in the PME group as compared to a 13.2% decrease in the PFES group ( $p=0.02$ ). This trial also compared PFES ( $n=32$ ) with vaginal cones ( $n=29$ ) and found no significant difference between groups. In the other four trials, all of which were unblinded, no significant group differences were found. Three studies comparing PFES to PME had small sample sizes, with 9 patients per arm (Smith 1996), 10 patients per arm (Hahn et al. 1991), and 23 patients per arm (Laycock and Jerwood 1993). It is likely that all these trials were underpowered to detect a difference or to demonstrate no difference. In the only trial that reported power calculations, Bo et al. estimated that 30 patients per arm should be enrolled to detect a difference of 1 standard deviation with a power of 80% and an alpha of 5%. In the final trial, with a slightly larger sample size, Olah et al. compared PFES ( $n=36$ ) to vaginal cones ( $n=33$ ), using

externally applied PFES (to abdomen and thighs) in contrast to the other trials using internal probes. This trial reported no significant group differences.

**Stress Incontinence: PFES plus PME compared to PME alone**

One trial by Blowman et al. (1991) compared PFES plus PME to sham PFES plus PME in the treatment of 14 women with stress incontinence (Table 3a and 3b). This small trial was randomized and double-blinded, but did not report a statistical comparison between treatment groups. For the first 4 weeks of home treatment, PFES consisted of 4-second work and 4-second rest cycles at 10Hz for 60 minutes per day. The next 2 weeks, PFES was administered at 35 Hz for 15 minutes per day.

This small trial does not demonstrate that addition of PFES to PME results in superior outcomes to PME alone. Outcomes were reported for 7 patients in the PFES plus PME group and 6 patients in the PME group. No statistical comparisons between groups were reported. Percent reduction in the median number of leaks per week in patient recorded diaries was 100% in the PFES plus PME and 52% in the PME group. The percent cure after 6 weeks of treatment was 86% (6 out of 7) for the PFES group and 16.5% (1 out of 6) for the sham group.

In studies of such small size, the likelihood that randomization may fail to produce comparable groups is greater than in larger studies. In this study, the control group appears to have a higher baseline frequency of accidents per week than did the PFES plus PME group. However, it is difficult to ascertain the actual difference because both baseline and outcome measures are reported as medians, not as means. At baseline the PME group had a median of 12.5 (range 1-31) accidents per week) compared to a median of 5 (range 1-14) accidents per week in the PFES plus PME group. Because of the baseline differences and small sample size in this single study, there is inadequate evidence to determine whether PFES has treatment effect additive to those of PME in treatment of urinary incontinence.

**Summary: Pelvic Floor Electrical Stimulation for Stress Incontinence**

Eleven controlled trials, of which all but one were randomized, reported outcomes of pelvic floor electrical stimulation in the treatment of stress incontinence. These trials do not provide strong and consistent evidence that PFES reduces the frequency and severity of incontinent episodes. Five trials (n=243), of which four were randomized, compared PFES to sham treatment in

**Table 3a. Controlled trials comparing PFES plus PME vs Sham PFES plus PME for Stress Incontinence - Methodologic Features**

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Blowman 1991	14 patients with SI.  Median age 45 years, range 33-68 years (sham), 42.5 years, range 38-64(PFES)	Double blind trial.  Randomized to PFES or sham device, randomization process not described.	<b>PFES and PME</b> (n=7, Nuerotech) PFES 60 minutes once/day, frequency 10Hz, intensity at level causing a minimal electrical sensation  <b>Sham device and PME</b> (n=6)  Both groups received individual instruction in PME. Sessions with therapist every two weeks.	NR	Pt recorded voiding diaries completed during first week of treatment and last week of treatment.	Low power to detect group differences

**Table 3b. Controlled trials comparing PFES plus PME vs Sham PFES plus PME for Stress Incontinence Outcomes**

Study/year	Patient/ Groups	PT recorded diaries  % % pts Measure Pre-Post- change1 improv2 improv2, %cure3	Pad test (grams)  % %pts% Measure Pre-Post- change1 improv2 improv2 °/ocure3	Comments
Blowman 1991	PFES plus PME (n=7)  Sham plus PME (n=6)	Leaks/wk* 5 0 100% NR 86%  Leaks/wk* 12.5 6 52% NR 16.5%  *Results reported as median leaks/wk  Reduction in frequency of incontinence significant for PFES group(p<0.05), NS for sham group	----- -----	

1 % change - Defined as the percent decrease In the frequency of incontinence over a specified time period, calculated by the following equation:



$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period} \times 100}{\text{pretreatment episodes/period}}$$

2 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

3 % cure - Defined as the percentage of patients with 100% decrease in frequency of incontinence, ie no incontinent episodes over the specified time period.

4 % change - Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference} \times 100}{\text{pretreatment pad weight difference}}$$

5 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

6 % cure - Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

### **Table bibliography:**

**Blowman C, Pickles C, Emery S et al. (1991).** Prospective double blind controlled trial of intensive physiotherapy with and without stimulation of the pelvic floor in treatment of genuine stress incontinence. *Physiotherapy*, 77(10):661-664.

patients with stress incontinence. Five trials (n=260) compared PFES to PME or to use of vaginal cones. One trial compared PFES plus PME to PME alone. These trials are relatively small (range 7-36 per arm) and the majority are inadequately powered to detect a difference or to demonstrate equivalence. The total number of patients studied is small relative to the population with stress incontinence.

Statistically significant results favoring PFES were reported in three trials comparing PFES to placebo. The group differences reported by Sand et al. (1995), although randomized and double-blinded, may be influenced by a high degree of variability in incontinent episodes in the control group, which consisted of only 17 patients. The trial by Yamanishi et al. (1997) enrolled 30 women and reported high rates of improvement and cure in the PFES group. This trial does not appear to be randomized and thus may be prone to selection bias. The single-blind, randomized trial by Laycock and Jerwood (1993), which enrolled 30 women, found a significant percent reduction in grams of urine leaked in the PFES group compared to placebo. This trial, however, had the potential for performance bias and attrition bias.

Only one trial comparing PFES to PME or vaginal cones reported statistically significant results. This 4-arm, single-blinded trial by Bo et al. (1999), found that a structured PME program (n=29) was superior to PFES (n=32). All three treatment groups showed efficacy on some outcome measures compared to the control group, but overall improvement was consistently greater for the PME group across all outcome measures. On the pad test, PME was significantly better than PFES on percent change in grams of urine leaked (78.2% vs. 13.2%,  $p=0.02$ ). There were no reported significant differences in other outcome measures between PME and PFES.

The trial by Luber et al. (1997) is of interest because the study population consisted of women (n=44) who had failed or declined treatment with pelvic muscle exercises. There was no significant difference between PFES and sham treatment

The ability to synthesize data from this body of literature is also limited by the large amount of variability in delivery of PFES across studies, a problem that has been documented previously in the literature (Fantl et al. 1996; Berghmans et al. 1998). Among the studies of PFES in stress incontinence, there was no standardization of treatment delivery. Treatment varied in location (home use vs. treatment in office), time of administration (once a day, multiple times/day for varying time periods), type and location of probes, as well as in the frequency and amplitude of the stimulation applied. It is possible that these variations in treatment delivery have an effect on the outcomes reported across the included studies.

### **Urge Incontinence: Placebo-Controlled Trials**

**Brubaker et al.** Brubaker et al. (1997) compared PFES with sham treatment in 146 women with stress incontinence (n=60), detrusor instability (n=28), or mixed incontinence (n=33). There were 27 (18%) dropouts over the 8 week trial; 14% in the PFES arm and 21% in the sham arm (NS). The results of this trial are largely limited to comparison of pre- and post-treatment urodynamic testing. Outcomes of primary interest to this assessment, improvement and cure as measured by voiding diaries or pad testing were not reported since the investigators were unable to analyze patient-reported diaries due to excessive missing entries. Thus, evidence from this trial is not included in the evidence tables.

Pre- and post-treatment urodynamic evaluation showed an improvement with PFES treatment in patients who had a pre-treatment diagnosis of detrusor instability; which also included patients with a diagnosis of mixed incontinence. Of the total of 61 patients with a diagnosis of detrusor instability, 33 were assigned to PFES treatment and 28 were assigned to sham treatment. The percentage of women with diagnosis of urge incontinence decreased from 54% to 27% after PFES treatment ( $p < 0.01$ ), whereas the change in pre and post-treatment diagnosis was nonsignificant with sham treatment (47% to 41%). Statistical significance of the difference in change between the groups was not reported.

No conclusions can be drawn from this trial. Between group differences on urodynamic testing were not reported. Moreover, outcomes of primary interest to this Assessment, improvement and cure as measured by voiding diaries or pad testing were not reported. It cannot be determined whether detrusor stability on provocative testing is an adequate surrogate for frequency and severity of incontinent episodes. More than half the patients with detrusor instability also had stress incontinence, for which PFES had no significant effect in this trial. Further, if an analysis of diaries and pad testing were restricted to patients with detrusor instability only, the sample size (approximately 14 per arm) might be inadequately powered to detect a difference.

**Urge Incontinence: Compared to Alternative Conservative Treatments**

Smith. Smith (1996) compared PFES with an anticholinergic drug for urge incontinence (Table 4a and 4b) . This trial randomized 38 women with urge incontinence to PFES or medication (propantheline, titrated dose) for a 4month period. There was one dropout among the 38 patients. Percent of patients with at least a 50% improvement in leaks per day measured by patient recorded diary was 50% for the PFES group and 35% for the medication group. There was no statistically significant difference between the groups. This trial may have inadequate power to detect a difference or to demonstrate no difference between treatments due to small sample size.

**Summary: PFES for Urge Incontinence**

Two randomized controlled trials investigated PFES in women with urge incontinence (n=66) or mixed incontinence (n=33). No conclusions can be drawn from either trial. The placebo controlled trial by Brubaker et al. (1997) did not report outcomes of primary interest to this assessment, improvement and cure as measured by voiding diaries or pad testing. The only outcome reported was pre- and post-intervention urodynamic testing, and no test of statistical significance of difference between treatment and control groups was reported. The second trial compared PFES with anticholinergic drug use for urge incontinence and found no significant difference. This trial may have inadequate power to detect a difference or to demonstrate no difference between treatments due to small sample size.

**Table 4a. Controlled trials comparing PFES vs alternative non-surgical treatments for Urge Incontinence - Methodologic Features**

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Smith 1996	38 women with urodynamically documented UI.  Mean age 62 years, range 44-82 years	Unblinded (?) trial.  Patients randomized to PFES or medication (propantheline). Randomization process not described.	Length of treatment – 4 months  PFES (n=18, Stimtech Products), home use 15-60 minutes twice/day, frequency 12.5Hz and 50Hz simultaneously, gradually increasing intensity to maximum 25mA. Medication (n=20).	PFES – 0/18  (0%)  Meds 0/20  (0%)	Pt recorded voiding diaries kept throughout the course of study.	

Table 4b. Randomized controlled trials comparing PFES vs alternative treatments for urge incontinence – outcomes

Study/year	Patient/Groups	PT recorded diaries  % % pts Measure Pre-Post- change1 improv2, %cure3	Pad test (grams)  % %pts% Measure Pre-Post- change1 improv2, %cure3	Comments
Smith 1996	PFES (n=18)  Medication (n=20)	Leaks/day 3.4 1.4 58.8% 50% 22%  Leaks/day 3.5 1.7 51% 35% 15%  No significant differences between groups	-----  -----	

1 % change - Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

2 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

3 % cure - Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e. no incontinent episodes over the specified time period.

4 % change - Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$

pretreatment pad weight difference

5 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

6 % cure - Defined as the percentage of patients with 100% decrease urine loss, i.e. no urine lost following the provocative maneuvers.

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### **Post-Prostatectomy Incontinence**

One study was identified that compared the combination of PFES and PME to PME alone (Moore et al. 1999) (Tables 5a and 5b). This was a randomized trial of men who had persistent incontinence 8 weeks or longer following radical prostatectomy. Sixty-three patients were randomized to standard treatment (including brief instruction on PME), intensive PME, or intensive PME plus PFES. Patients in the combination group had PFES performed in clinic once/week for a total of 12 weeks. They also received instruction in PME once per week. Patients in the intensive PME group received instruction in PME twice/week for the study period.

All three groups showed significant improvement over the course of the study. There were no significant differences in percent change in grams of urine leaked by pad test (PFES plus PME: 66%, PME: 85%, standard care: 73%). The ability to detect group differences may have been limited by a large degree of spontaneous improvement, which might be expected to occur in this population. This trial does not demonstrate that the addition of PFES to PME improves outcomes compared to PME alone in this population.

### **SUMMARY**

**Stress Incontinence.** Eleven controlled trials, of which all but one were randomized, reported outcomes of pelvic floor electrical stimulation in the treatment of stress incontinence. The delivery of PFES varied considerably across trials. Treatment varied in location (home use versus treatment in office), time of administration (once a day, multiple times per day for varying time periods), type and location of probes, as well as in the frequency and amplitude of the stimulation applied. The results of the trials were

not consistent. Overall, this body of literature does not provide strong and consistent evidence that PFES reduces the frequency and severity of incontinent episodes.

Five trials (n=243), of which four were randomized, compared PFES to sham treatment in patients with stress incontinence. An additional five trials (n=260), compared PFES to PME or to use of vaginal cones. One trial compared PFES plus PME to PME alone. These trials are small (range 7-36 per arm) relative to the population with stress incontinence, and the majority are inadequately powered to detect a difference or to demonstrate equivalence.

Statistically significant results favoring PFES on at least one relevant outcome measure were reported in three trials comparing PFES to placebo. The group differences reported by Sand et al. (1995), although randomized and doubleblinded, may be influenced by a high degree of variability in incontinent episodes in the control group, which consisted of only 17 patients. In addition, there was potential for selection bias and attrition bias in this study. The trial by Yamanishi et al. (1997) enrolled 30 women and reported high rates of improvement and cure in the PFES group. This trial does not appear to be randomized and thus may thus be prone to selection bias. The single-blind, randomized trial by Laycock and Jerwood (1993), which enrolled 30 women, found a significant percent reduction in grams of urine leaked in the PFES

**Table 5a. Controlled trials comparing PFES plus PME versus sham PFES plus PME for postprostatectomy incontinence – methodologic features**

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Moore 1999	63 men > 8wks post prostatectomy with persistent incontinence. Mean age 67 years, range 49-77 years.	Pts randomized to standard treatment control(including PME), intensive PME, or intensive PME plus PFES. Randomization process not described.	PFES(n=22) (InCare anal electrode). PFES in clinic once/week for 30 minutes, frequency 50Hz, intensity adequate to induce muscle contraction. PFES sessions alternating with PME instruction for 30 minutes once/week. Intensive PME(n=20). Instruction in PME by therapist 30 minutes twice/week. Standard treatment (n=21). Written and verbal instructions in PME given at postoperative visits. Length of treatment – 12 weeks	PFES plus PME 3/22 (13.6%) PME 2/20 (10%) Ctrl 0/21 (0%)	Standardized 24 hour pad test.	

**Table 5b. Controlled trials comparing PFES plus PME versus sham PFES plus PME for post-prostatectomy incontinence – outcomes**

Study/year	Patient/ Groups	PT recorded diaries  % % pts Measure Pre- Post- change1 improv2 improv2, %cure3	Pad test (grams)  %%pts% Measure Pre- Post- change1 improv2 improv2 %/cure3	Comments
Moore 1999	PFES plus PME (n=22)  PME (n=20)  Ctrl (n=21)	-----  -----  -----	453 156 66% NR NR  566 87 85% NR NR  386 104 73% NR NR  No significant differences among groups	Large improvement in all groups, limiting ability to detect a treatment effect

1 % change - Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

2 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

3 % cure - Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e., no incontinent episodes over the specified time period.

4 % change - Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$

$$\text{pretreatment pad weight difference}$$

5 % pts improv - Defined as the percentage of patients with 50% or greater decrease in the amount of urine' 165t in-grams following provocative maneuvers.

6 % cure - Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

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group compared to placebo, but found no difference in the frequency of incontinence between groups. This trial also had the potential for performance bias and attrition bias.

In the other two trials of PFES versus sham PFES (Brubaker et al. 1997; Luber et al. 1997), there were no group differences in any of the relevant outcomes for patients with stress incontinence. The results by Brubaker et al. are limited by extensive missing data, precluding analysis of patient recorded diary data. The trial by Luber et al. (1997) is of interest because the study population was women (n=44) who had failed or declined treatment with pelvic muscle exercises.

Five randomized controlled trials, including a total of 260 patients, compared PFES to alternative conservative treatment (PME or vaginal cones) for treatment of stress



incontinence. Only one trial reported statistically significant results. This 4-arm, single-blinded trial by Bo et al. (1999), found that a structured PME program (n=29) was superior to PFES (n=32) on percent improvement on a standardized pad test. In this trial there was a 78.2% decrease in urine loss in the PME group as compared to a 13.2% decrease in the PFES group (p=0.02). This trial also compared PFES (n=32) with vaginal cones (n=29) and found no significant difference between groups. In the other four trials, all of which were unblinded, no significant group differences were found.

Three studies comparing PFES to PME had small sample sizes, with 9 patients per arm (Smith 1996), 10 patients per arm (Hahn et al. 1991), and 23 patients per arm (Laycock and Jerwood 1993). It is likely that all these trials were underpowered to detect a difference or to demonstrate no difference. In the only trial that reported power calculations, Bo et al. estimated that 30 patients per arm should be enrolled to detect a difference of 1 SO with a power of 80% and an alpha of 5%. In the final trial, with a slightly larger sample size, Olah et al. compared PFES (n=36) to vaginal cones (n=33), using externally applied PFES (to abdomen and thighs) in contrast to the other trials using internal probes. This trial reported no significant group differences.

**Urge Incontinence.** Two randomized controlled trials investigated PFES in women with urge incontinence (n= 66) or mixed incontinence (n=33). No conclusions can be drawn from either trial. The placebo controlled trial by Brubaker et al. (1997) did not report outcomes of primary interest to this assessment, improvement and cure as measured by voiding diaries or pad testing. The only outcome reported was pre- and post-intervention urodynamic testing, and no test of statistical significance of difference between treatment and control groups was reported. The second trial (Smith 1996) compared PFES with an anticholinergic drug for urge incontinence and found no significant difference. This trial may have inadequate power to detect a difference or to demonstrate no difference between treatments due to small sample size.

**Post-prostatectomy Incontinence.** A randomized trial of 63 men with persistent incontinence more than 8 weeks post-prostatectomy, compared PFES plus PME to PME alone and found no difference between groups. This trial does not demonstrate that the addition of PFES to PME improves outcomes compared to PME alone.

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