



**TITLE:** Electrical Stimulation for the Treatment of Urinary Incontinence in Women

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## ELECTRICAL STIMULATION FOR THE TREATMENT OF URINARY INCONTINENCE IN WOMEN

### INTRODUCTION

The California Technology Assessment Forum has been asked to review the scientific literature on the use of pelvic floor electrical stimulation as a treatment for urinary incontinence in women.

### BACKGROUND

Urinary incontinence is the involuntary loss of urine from the urethra that is sufficient to be a social or hygienic problem (Fantl *et al.*, 1996). It is a multifactorial syndrome involving the intersection of neurourinary pathology, age-related factors and comorbid conditions. The prevalence varies with the definition used and the age and sex of the population. Overall, urinary incontinence affects about 15% of the ambulatory adult population or approximately 13 million adults in the U.S. (Resnick and Griffiths, 2003). Risk factors for the development of urinary incontinence in women include childbirth, hysterectomy, recurrent urinary tract infections, medications such as diuretics and sedative-hypnotics and alpha blockers, the presence of two or more co-morbid diseases such as CHF and COPD, diabetes, advancing age and increased body mass index (Holroyd-Leduc and Strauss, 2004). Dementia is also associated with urinary incontinence. Alzheimer's and multi-infarct disease damage cortical and subcortical inhibitory centers, leading to uninhibited bladder contractions and urinary incontinence. Severely demented individuals remain continent if they have preserved mobility (Brandeis *et al.*, 1997).

Most persons with urinary incontinence are women. Up to 35% of women over the age of 60 in the U.S. are bothered by urinary incontinence, and at least half of all nursing home residents are affected (Berghmans *et al.*, 1998). Urinary incontinence brings significant costs to the individual and to society. For the individual, it is associated with social isolation, increased depression, lower self-rated health and impaired quality of life and psychological distress (Holroyd-Leduc and Strauss, 2004; Burgio *et al.*, 2001). Urinary incontinence-related costs in the U.S. are estimated at \$12.4 billion for women (in 1995 dollars) though all cost estimates likely underestimate the impact of the problem, as many patients remain undiagnosed. Fewer than half of individuals with urinary incontinence living in the community consult health care providers about the problem (Fantl *et al.*, 1996). The majority of the costs associated with urinary incontinence reflect management (e.g., protective garments) rather than curative treatment (Resnick and Griffiths, 2003).

There are several different types of urinary incontinence in women including urge urinary incontinence (UUI), stress urinary incontinence (SUI), mixed incontinence and overflow incontinence. Urge incontinence is defined as the uncontrolled loss of urine that is preceded by a strong, unexpected urge to void. It is unrelated to position or activity (Stoller *et al.*, 2004). Urge incontinence is generally due to detrusor overactivity. Stress incontinence is associated with activities that cause an increase in intra-abdominal pressure (e.g. sneezing or coughing). Laxity of the pelvic floor musculature, secondary to childbirth or surgery, is thought to result in diminished sphincter dysfunction. Mixed incontinence is a result of a combination of SUI and UUI. The least common type, overflow incontinence, results from over-distention of the bladder usually from obstruction, or a neurological impairment such as spinal cord injury or end-stage diabetes.

Treatment of urinary incontinence can be divided into non-pharmacologic, pharmacologic and surgical. Non-pharmacologic therapies consist of behavioral interventions such as PFMT, biofeedback, vaginal weights, bladder training and pelvic stimulation. Of these, PFMT and exercises are strongly supported on the basis of multiple randomized trials (Borello-France and Burgio, 2004) and were found to be an effective treatment for adult women with stress or mixed incontinence by a Cochrane review (Hay-Smith *et al.*, 2001). Behavioral treatment for UUI is based upon two general principles: frequent voluntary voiding to keep the bladder volume low and training of central nervous system and pelvic mechanisms to inhibit/ablate detrusor contractions (Bladder training). Behavioral therapy for SUI begins with pelvic muscle exercises (PME), also known as Kegel exercises (KE). PME strengthen the muscular components of the urethral closure mechanism. It is based on the rationale that a strong and fast pelvic floor muscle (PFM) contraction will clamp the urethra, create increased intraurethral pressure and prevent leakage of urine when the intra-abdominal pressure rises abruptly (Hay-Smith *et al.*, 2001).

Pharmacologic treatments mainly include anticholinergic/antimuscarinic drugs to inhibit involuntary detrusor contractions in urge incontinence and alpha-adrenoreceptor agonists for stress incontinence. A variety of surgical techniques have been evaluated for stress incontinence including open retropubic colposuspension, suburethral sling procedure and bladder neck needle suspension. Surgery is associated with a high cure rate, but is invasive and can be associated with significant morbidity. There is insufficient evidence to compare surgery with other interventions and most experts recommend that patients undergo non-surgical options first (Holroyd-Leduc and Strauss, 2004).

### **Pelvic Floor Electrical Stimulation**

Pelvic floor electrical stimulation (PFES) has been proposed as a treatment for patients who do not benefit from or cannot utilize behavioral or drug therapy, or, as an adjunct to these therapies. Electrical stimulation was first proposed in 1963 to address urinary and fecal incontinence. Electrical stimulation is believed to work through three

different mechanisms: by direct stimulation of motor nerves supplying the pelvic floor and external urethral sphincter that results in muscle contraction, thereby strengthening the muscles; by exhausting afferent sensory nerves from the bladder thereby suppressing overactive bladder contractions; and by blocking irritative bladder symptoms via the gate control theory (Klausner and Steers, 2004). PFES can be performed in a clinical setting or with intravaginal devices designed for home use (Borello-France and Burgio, 2004). Implantable electrodes in the PFMs and implantable sacral nerve stimulation have also been studied, however, these techniques are beyond the scope of this review.

The device used in PFES includes the internal probe that delivers the electrical current and an external device that controls the electrical stimulation. The methods of PFES vary in location, stimulus frequency, stimulus intensity, pulse duration, pulse to rest ratio, treatments per day, treatment days per week, treatment duration of each session and overall treatment duration and location of treatment—home or office (Fantl *et al.*, 1996). The most practical regimens employ an electrical stimulation frequency of 10 to 50 Hz, for 15 to 20 minutes, once or twice daily at the maximum intensity that the patient can tolerate without pain. Generally, 50 Hz is used for SUI and 10-20 Hz for UUI. Sessions are daily for 15-30 minutes at the maximal intensity, for 4-12 weeks. Trials have examined the impact of floor electrical stimulation (FES) alone or in conjunction with other behavioral modalities. Adverse reactions are generally minimal and include pain and discomfort (Yasuda and Yamanishi, 1999).

This review considers the benefits and risks of non-implantable electrical stimulation for urinary incontinence in women. The main types of incontinence addressed in this review are stress incontinence, urge incontinence and mixed incontinence. PFES in the treatment of urinary incontinence in adults was the subject of a Blue Cross and Blue Shield Association TEC review, published in 2000, which concluded that the technology did not meet the TEC criteria. This review will consider the entire peer reviewed literature but will focus on randomized controlled trials published from the year 2000 to the present.

**TA Criterion 1: The technology must have the appropriate regulatory approval.**

Several brands of pelvic floor electrical stimulators have been cleared by the FDA for marketing under section 510(k) of the Federal Food Drug and Cosmetic Act, since 1991.

**TA criterion 1 is met**

**TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.**

There have been 17 randomized trials of PFES for treatment of urinary incontinence in women published in peer-

reviewed journals. Some of these trials have included men.

The most commonly used measure of urinary incontinence treatment efficacy is a reduction in urinary incontinence episodes, variably measured as the reduction in mean number of daily episodes, percent reduction from baseline or reduction in leakage volume. Cure is usually defined as complete absence of urinary incontinence. Other outcome measures frequently used are total number of daytime and nighttime continent voids, bladder capacity (or mean voided volume) and post void residual volume.

However, these measures may not reflect the patient's perception of improvement. Patient-based outcomes may be better assessed using general satisfaction questions, relief of most bothersome aspect of urinary incontinence or urinary incontinence-specific quality of life measures. General health-related quality of life measures (such as the Medical Outcomes Study Short Form-36) largely have proved insensitive to changes in urinary incontinence after treatment (Burgio *et al.*, 2001).

Most of the trials follow patients for no more than 6 months, limiting our ability to conclude if the intervention had a long-term impact on continence. One small trial (Bratt *et al.*, 1998) surveyed 30 women with urge incontinence, ten years after treatment with transvaginal electrical stimulation. They found that most of the women still had symptoms of urge incontinence, though 60% reported that they were satisfied with the treatment. Interestingly, 70% of the cohort reported problems with stress incontinence.

In spite of the large number of randomized clinical trials, it is difficult to draw conclusions from the literature about the efficacy of PFES for the treatment of urinary incontinence due to the significant variability in their treatment protocols, the patient populations studied, the equipment used and their outcome measurements.

**TA criterion 2 is not met**

Levels of Evidence: 2 and 5.

**TA Criterion 3: The technology must improve the net health outcomes.**

**RANDOMIZED TRIALS:**

**PFES vs. Placebo/Sham**

Barroso *et al.* (2004) report on a double blind, randomized, controlled trial of 36 women (24 intervention and 12 controls) with stress, urge or mixed incontinence recruited from an outpatient OB/GYN clinic in Brazil. Exclusion criteria included: cardiac pacemaker, pregnancy, symptoms or signs of urogenital atrophy and use of medication for urinary symptoms. Patients in the study group with urge or mixed incontinence received equipment programmed for a

frequency of 20 Hz; for stress incontinence, the frequency was 50Hz. The control group received the same equipment but with no stimulus. All patients were instructed to use the equipment at home, twice daily for 12 weeks. All participants kept a voiding diary to record urinary frequency and leakage. The authors report that patients in the electrical stimulation arm reported a significantly greater reduction in loss of urine and an increase in bladder capacity, as measured by cystometry. However, patients in the intervention group reported significantly more incontinence at baseline than did the sham-control patients, and 11 of 24 patients in the intervention group had undergone previous urogenital surgery, compared to 3 of 12 in the sham-control group. These differences raise questions about the randomization process and the validity of the outcomes in this small, poorly described study.

Yamanishi *et al.* (2000) report on a double blind, randomized, controlled trial of 68 patients in Japan (39 women, 29 men) with urinary incontinence secondary to detrusor overactivity. Detrusor overactivity was defined as involuntary detrusor contractions of more than 15 cm of water during bladder filling (a standard definition). Women used a vaginal electrode and self-administered stimulation for 15 minutes, twice daily for 4 weeks. The sham device was identical in appearance to the active device. Patients recorded the number of voids, leaks and number of pad changes, as well as subjective impressions and quality of life indicators. Patients were well matched except that the sham group was significantly older (73 years vs. 67.5 years). Seven patients (21.9%) in the active group and one (3.6%) in the sham group were cured ( $P=0.03$ ); 26 patients (81.3%) in the active group and 9 (32.1%) in the sham group improved ( $p=0.001$ ). Improvement was defined as a decrease in incontinence of at least 50%. These results persisted when the women were analyzed separately. There was no significant difference between the groups in the daily frequency of pad changes. Adverse effects were minimal and did not differ between the groups. Seventeen of the 26 patients in the active group, who were cured or improved, were followed up monthly for an average of 8.9 months after treatment. Of these, ten patients had a relapse of incontinence.

Jeyaseelan *et al.* (2000) report on a randomized, sham-controlled trial of 27 patients with stress incontinence. Patients were assessed using perineometry, digital assessment, pad testing, quality of life measures and the Incontinence Impact Questionnaire. They found no significant differences between groups in any of the objective measures of incontinence.

Luber and Wolde-Tsadik (1997) conducted a randomized placebo-controlled trial of 44 women with stress incontinence in the U.S. who had failed or declined treatment with PME. Stimulation took place in two, 15 minute sessions / day, over 12 weeks. As in other trials, control patients were given an identical device that delivered no electrical stimulation. Compliance was measured with an internal memory system within the stimulation unit. At baseline and again at 12 weeks, patients were evaluated using voiding diaries, an incontinence questionnaire and urodynamic studies. Patients were considered a subjective failure if they reported minimal or no improvement in symptoms and a cure if they reported complete resolution of their symptoms. Objective failure was defined as a positive stress test on repeat studies. Fifty-four women enrolled and 44 completed the trial, 20 in the treatment group

and 24 in the control group. Overall, they found no statistically significant difference in the rate of subjective improvement, subjective cure or objective cure between the treatment or control group. Additionally, no difference was observed between treatment and control group, with respect to the number of incontinence episodes and in objective measures, such as cystometry. Overall, 41% of the treated group and 42% of the placebo group had an objective cure or reported subjective cure or improvement. The authors concluded that electrical stimulation of the pelvic floor was no more effective in treating stress incontinence than was the retention of the placebo probe for an equal length of time.

Brubaker *et al.* (1997) conducted a prospective, double blind, randomized, clinical trial of 121 women with either urinary incontinence caused by detrusor instability (n=28) or genuine stress incontinence (n=60) or both (mixed incontinence) (n=33). Participants used the assigned device for eight weeks at a standard stimulation considered to be in the upper range for urge incontinence and the lower range for stress incontinence. Identical pre-intervention and post-intervention assessment included multichannel urodynamic testing, quality-of-life scale and urinary diaries. A total of 121 women completed this study at four North American urogynecology centers. Detrusor instability was cured (stable on provocative cystometry) in 49% of women with detrusor instability who used an active electrical device ( $p = 0.0004$ , McNemar's test), whereas there was no statistically significant change in the percentage with detrusor instability in the sham device group. However, improvement and cure, as measured by voiding diaries or pad testing, were not reported due to non-compliance on the part of the study participants. There was no statistically significant difference between the pre-intervention and post-intervention rates of genuine stress incontinence for either the active device group or the sham device group.

Sand *et al.* (1995) report on a multi-center, randomized, sham-controlled trial of women with stress incontinence. Thirty-five women used the active device and 17 subjects used the sham device. They report that active device patients had significantly greater improvements in weekly and daily leakage episodes, pad testing and vaginal muscle strength when compared with control subjects. However, there are several methodological problems with this study. The sham group was statistically significantly older than the active treatment group (57.7 vs. 50.9) and had more baseline leakage episodes / week than the PFES group (20 vs. 14). The drop-out rate was higher in the PFES group (20.6% vs. 6%) and it is not clear from the paper how much of the analysis was on an intent-to-treat basis. Finally, it is curious that they found a worsening of incontinence (increase in leakages) in the sham group over the 12-week study. This unlikely finding partly explains the significant differences that emerged within and between the groups.

Laycock and Jerwood (1993) report on a randomized, single-blind, clinic based trial of 30 women with stress incontinence. Patients in the PFES arm showed a significant decrease in grams of urine leaked, compared to placebo (on the pad test), however, the percent of patients cured was not statistically significant. Other trials of PFES

vs. placebo were either too small (e.g. Blowman *et al.*, 1991) or methodologically flawed due to lack of randomization (e.g. Yamanishi *et al.*, 1997), to be considered in this review.

### **PFES vs. Behavioral Treatment**

Wang *et al.* (2004) report on a single blind randomized trial from Taiwan of pelvic floor muscle training (PFMT), biofeedback assisted pelvic floor muscle training (BAPFMT) and electrical stimulation in the treatment of overactive bladder. Overactive bladder refers to a syndrome of urgency, frequency or nocturia in the absence of overt pathology, with or without urge incontinence. The PFMT subjects were instructed in home PME to be performed at least three times daily. The BAPFMT arm were trained with an intravaginal electromyogram probe twice weekly at the center, and the PFES subjects underwent electrical stimulation for 20 minutes twice weekly at the research unit. Overall, 137 women were recruited and 120 were randomly allocated. Of these, 17 patients dropped out and were not included in the final analysis of the results. There were significant differences between the groups after randomization in the number of prior pregnancies (more in the PFES group), number of women in menopause (less in the PFES group) and in baseline urinary leakages / day (PFMT, 0.86 +/- 1.80; BAPFMT, 0.92 +/- 1.77; PFES, 2.09 +/-; P=0.046). Patients in all groups improved on the subjective assessment of urinary incontinence with no statistical significant difference between the groups. They did find a statistically significant difference between the groups in episodes of leakage / day, favoring the PFMT and BAPFMT over the PFES group, but did not use this as an outcome measure "because of the large number of incomplete records which could have resulted in a statistical bias." Subjects in the PFES arm achieved statistically significant improvement in the Kings Health Questionnaire (KHQ) in the domains of emotions and severity measures and greater change in the overall score. Overall, it is not possible to conclude from this study that PFES is superior to PFMT or BAPFMT for the treatment of overactive bladder.

Sung *et al.* (2000) report on a study that compared PFES-biofeedback vs. pelvic floor muscle exercises (PFME) in 60 Korean women with stress incontinence. The PFME group received special training, a videotape, asked to do the exercises at home (frequency unknown) and visit the clinic once / week to assess compliance. The PFES-biofeedback group received treatment for 20 minutes, twice weekly for 6 weeks. They found that PFES-biofeedback group showed significantly increased maximal pelvic muscle contraction pressure, decreased urine leakage and frequency compared with the PFME arm. However, the design of this study makes it impossible to separate the independent contribution of biofeedback from PFES in these outcomes.

Spuijt *et al.* (2003) report on a randomized trial of electrical stimulation vs. daily KE program in elderly women with stress, urge or mixed incontinence. Fifty-one women enrolled and 37 were randomized into one of two arms: PFES for 30 minutes 3 times / week for 8 weeks vs. instructions on how to perform KE at home, at a baseline visit, with no intervening instructions. Outcome measures included the 48-hour pad test (grams of urinary leakage/day), pelvic

muscle strength and detrusor instability. They found no significant improvement in objective or subjective outcome variables in the subjects treated with PFES, compared with KE.

Bo *et al.* (1999) randomized 107 women with stress incontinence into one of four groups: pelvic floor exercises (n=25), electrical stimulation (n=25) of 30 minutes/day, vaginal cones (n=27) for 20 minutes a day and an untreated control group. The main outcome measure was a pad test and self-report of severity. They found that reduction in leakage on the pad test was greater in the exercise group than in the electrical stimulation or vaginal cone group. There were no significant differences in other outcome measures between PME and PFES. The authors conclude that training of the PFMs is superior to electrical stimulation and vaginal cones in the treatment of genuine stress incontinence.

Other trials that compared electrical stimulation to behavioral interventions have reached similar conclusions. Smith (1996) compared PFES with PME in 57 women with stress and urge incontinence. Women with stress incontinence were further randomized to receive PFES vs. KE, while those with urge incontinence received an anticholinergic medication or PFES. After 4 months of therapy, they found that most women improved in objective and subjective measures, but found no statistically significant differences between the groups. The small sample size in each arm was a factor. Olah *et al.* (1990) compared PFES to vaginal cone treatment in women with stress incontinence. All women also received instruction in PME. No differences were found between groups at the six-month follow-up, though the trend in improvement on the pad test favored the vaginal cones arm. Hahn *et al.* (1991) found no statistically significant difference in outcomes, at six months, in 20 patients randomized to PFES or PME with SUI. Blowman *et al.* (1991) reported on a small trial of 14 women with stress incontinence, all of which were treated with PFME then randomized to electrical stimulation vs. placebo stimulation. They found that 4 of 6 women in the placebo arm "required" surgery after the treatment compared with none of the seven women in the PFES group. The small numbers and numerous methodological problems in this trial make firm conclusions impossible.

### **Systematic Reviews**

Berghmans *et al.* (1998) published a systematic review of randomized clinical trials of conservative treatment of SUI in women. Although she identified six trials that report electrical stimulation to be more effective than sham stimulation, she points out that there was no consistency in the type of stimulation or the stimulation parameters used in these trials, making it difficult to interpret their conclusions (Berghmans *et al.*, 1998). She concluded that: "Trends in the evidence suggest that active stimulation is more effective than sham stimulation, but electrical stimulation may be no more effective than PFM exercises alone or other physical therapies. . . . It seems that further investigation of electrical stimulation is required to establish its efficacy for SUI, a view also supported by others."

The Cochrane library (Hay-Smith *et al.*, 2001) reviewed the literature on PFMT for urinary incontinence in women. In this review, they concluded that PFMT is better than no treatment or placebo treatment for women with SUI and/or

mixed incontinence. Because of inconsistencies in the technique and other limitations in the literature, they found it difficult to reach firm conclusions regarding the benefit of PFES as an alternative or adjunct to PFMT. However, based on limited evidence to date, they concluded that PFMT may be more effective than PFES and the adverse rates appear to be higher with PFES. Further, they concluded that there is no good evidence to suggest that there is benefit of adding PFES to PFMT for women with SUI. The Cochrane review of FES has been withdrawn, pending revision.

### **Pending Trials**

There are no known clinical trials of PFES currently in process.

### **Patient Risks**

Adverse events associated with PFES are generally mild and not significantly different than that seen with sham treatment. There are no known long term adverse consequences associated with PFES.

In sum, of the nine trials comparing PFES to placebo, only three (Barroso *et al.*, 2004; Yamanishi *et al.*, 2000; Sand *et al.*, 1995) found statistically significant results in favor of electrical stimulation. However, each of these trials suffered from methodological flaws outlined above, and there was no consistency between the trials in type of stimulation and the stimulation parameters. None of the eight trials of PFES vs. behavioral treatment conclusively demonstrated the superiority of PFES. On the basis of the current evidence, it is not possible to conclude that PFES improves net health outcomes in women with urinary incontinence.

### **TA criterion 3 is not met**

#### **TA Criterion 4: The technology must be as beneficial as any established alternatives.**

Other strategies that have been used to treat urinary incontinence in women include behavioral interventions such as PFMT, biofeedback, vaginal weights and bladder training; pharmacological interventions and surgery. PFMT was first introduced in 1948 by Arnold Kegel to treat women with urinary incontinence. In the management of SUI, it is based on the rationale that pelvic floor contraction will clamp the urethra and thereby increase intraurethral pressure, thus, preventing leakage of urine during abrupt increases in intra-abdominal pressure. The rationale for PFMT is less clear in urge incontinence, though one theory holds that PFMT may lead to reflex inhibition of detrusor contractions (Borello-France and Burgio, 2004). Results from several randomized trials strongly support the use of PFMT as a safe and effective treatment in the management of stress, urge and mixed incontinence in women. A recent Cochrane review concluded that PFMT is superior to placebo treatment for women with stress and/or mixed

incontinence (Hay-Smith *et al.*, 2001). The frequency and intensity of PFMT needed for sustained response is less clear.

For PFMT to be effective, the patient must learn to contract the appropriate muscles without straining, which can lead to increases in intra-abdominal pressure. BAPFMT has been used as an adjunct to teach patients proper pelvic muscle contraction. Results from randomized trials, however, do not confirm that biofeedback improves outcomes over PFMT alone (Hay-Smith *et al.*, 2001; Berghmans *et al.*, 1998). Vaginal cones also have been used to promote strengthening of the pelvic floor musculature, particularly in the treatment of stress incontinence. Results from randomized trials do not support their use over PFMT (Holroyd-Leduc and Strauss, 2004).

A variety of pharmacological therapies have been used in the treatment of urinary incontinence in women. For urge incontinence, anti-cholinergic/antimuscarinic medications have been found to be superior to placebo in subjective improvement or cure. Tricyclic antidepressants have also been shown to be of benefit (Holroyd-Leduc and Strauss, 2004). For stress incontinence, the role of pharmacotherapy has been more limited. Research has focused recently on alpha-1 A selective adrenoceptor agonists with the theory that these agents might effectively increase the bladder outlet resistance and therefore, limit symptoms in women with SUI. Clinical trials are still ongoing (Klausner and Steers, 2004). Other treatments, such as botulinum toxin for urge incontinence, are far on the horizon.

Surgery is an option for women with SUI who have failed more conservative treatment approaches. A variety of surgical techniques have been evaluated. The goals of surgical treatment are to stabilize the bladder neck to prevent descent with increased intra-abdominal pressure and to create a stable fascial layer for urethral compression. A recent Cochrane review concluded that open retropubic colposuspension (Burch procedure) was the most effective treatment modality for SUI, with 85 to 90 % of patients content after one year and 70 % after five years (Lapitan *et al.*, 2003). Comparing the different surgical procedures is difficult due to variations in patient selection, experience of the surgeon, diagnostic methods, techniques, outcome criteria and length of follow-up. Potential complications of surgery include urinary retention (generally short term), detrusor overactivity, injury to the bladder or ureter, infection, hemorrhage and enterocele.

In sum, effective treatments are currently available for the treatment of urinary incontinence that has demonstrated to be more beneficial than PFES. These include PFMT alone for stress and mixed incontinence, behavioral training including bladder training and anti-cholinergic medication for urge incontinence. Surgery has been shown to be effective for women who have failed conservative measures. There is insufficient evidence from randomized clinical trials to conclude that PFES is as beneficial as these alternative therapies. In addition, PFES has not been shown to improve management of urinary incontinence in women when used as an adjunct to PFMT.

To date, PFES has not been shown to be as effective as behavioral or pharmacological therapy in the treatment of stress, urge and mixed incontinence in women.

TA criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

PFES has not been shown to improve outcomes in clinical trials.

TA criterion 5 is not met.

**Abbreviations used in this assessment:**

PFM – pelvic floor muscle

PFMT – pelvic floor muscle training

PFES – pelvic floor electrical stimulation

BAPFMT – biofeedback assisted pelvic floor muscle training

KHQ – Kings Health Questionnaire

PFME – pelvic floor muscle exercises

KE – Kegel exercise

PME – pelvic muscle exercise

SUI – stress urinary incontinence

UUI – urge urinary incontinence

FES – floor electrical stimulation

## **RECOMMENDATIONS OF OTHERS**

### **Blue Cross Blue Shield Association (BCBSA)**

The BCBSA TEC Medical Advisory Panel reviewed the use of PFES in the treatment of urinary incontinence in adults in June 2000 and determined that this technology did not meet TEC criteria.

### **Centers for Medicare and Medicaid Services (CMS)**

In October 2000, the CMS released a statement noting expanded coverage of urinary incontinence therapies. The release indicated that Medicare would cover PFES and biofeedback for Medicare patients with stress and/or urge incontinence for which pelvic muscle exercise has not worked. PFES is excluded as a primary therapy.

### **California Urological Association (CUA)**

A representative of the CUA attended the meeting and provided testimony in favor of the recommendation.

### **American College of Obstetricians and Gynecologists, District IX (California) (ACOG)**

The California chapter of ACOG provided a representative to the meeting. Testimony was provided stating:

"ACOG recognizes that there is bias and many unanswered questions regarding the effectiveness of PFES that most likely require better designed and better executed studies. Nonetheless, their opinion is that PFES may be efficacious for both stress and urge incontinence in women, in whom traditional treatment approaches have failed. They do, however, state that it may be no better than other therapies available, including PME, bladder retraining and medications for urge incontinence. ACOG supports the availability of PFES devices for patients because they are convenient, have no side effects and can be used in the convenience of the home, avoiding travel to the physician's office and time away from work."

## CONCLUSION

Urinary incontinence, defined as involuntary leakage of urine, affects over 13 million Americans and disproportionately impacts women and the elderly. It imposes a significant psychological impact on patients, their families and caregivers; and it is a major cause of institutionalization of the elderly (Fantl *et al.*, 1996). Urinary incontinence is underreported by patients and families, often going undiagnosed and under-treated. Current treatment options for urinary incontinence include pharmacologic options; non-pharmacologic approaches such as PFMT, behavioral training including bladder training, vaginal cones and electrical stimulation and pharmacologic options; and surgery. Of these, only PFMT and behavioral training including bladder training have been shown in randomized trials to be an effective first line therapy for women suffering from urinary incontinence.

Of the nine trials comparing PFES to placebo, only three (Barroso *et al.*, 2004; Yamanishi *et al.*, 2000; Sand *et al.*, 1995) found statistically significant results in favor of electrical stimulation. However, because of variation in the type of stimulation used, the parameters of the stimulation and other methodological considerations discussed above, it is not possible to conclude that PFES is superior to placebo/sham for stress, urge or mixed incontinence. A recent review lamented: "The ideal electrical parameters for pelvic stimulation have not yet been well established." (Barroso *et al.*, 2004) Similarly, trials comparing electrical stimulation to PFME, or combined with these behavioral treatments, have generally yielded negative findings.

Recent systematic reviews of this subject have reached similar conclusions. The Cochrane library recently reviewed the literature on PFMT for urinary incontinence in women (Hay-Smith *et al.*, 2001). In this review, they concluded that PFMT is better than no treatment or placebo treatment for women with SUI and/or mixed incontinence. Because of inconsistencies in the technique and other limitations in the literature, they found it difficult to reach firm conclusions regarding the benefit of PFES as an alternative or adjunct to PFMT. However, based on limited evidence to date, they concluded that PFMT may be more effective than FES, and the adverse rates appear to be higher with PFES. Further, they concluded that there is no good evidence to suggest that there is benefit of adding PFES to PFMT, for women with SUI.

A potential confounder in all of the trials of PFES is the fact that it is difficult to adequately blind patients in an intervention like electrical stimulation; a percentage of patients in the active arm will realize that they are receiving the intended treatment. Some researchers attempt to correct for this potential bias by informing patients that some active treatments may not cause a sensation. Few, if any, trials asked women if they could identify into which arm they were randomized. This problem, however, is more likely to bias results in favor of the active treatment.

The majority of the trials to date of PFES for urinary incontinence were conducted in women with stress or mixed incontinence. Some experts point out, however, that electrical stimulation should not be expected to produce significantly positive results in women with stress incontinence because electrical stimulation has limited efficacy in stimulating denervated muscle. The underlying problem for many women with stress incontinence is that their PFMs became partially denervated during vaginal delivery. They argue that the proper role of PFES may be to help facilitate bio-feedback enhanced pelvic floor exercises (Luber and Wolde-Tsadik, 1997). For the most part, the trials to date do not support this assertion. PFES has been less impressive as an adjunctive technique to behavioral interventions such as pelvic floor exercises and biofeedback than it has as a stand-alone vs. placebo.

Finally, it has been asserted that a particular sub-group of women may benefit from PFES, such as those who are initially unable to voluntarily contract their PFMs. PFES may help those women achieve continence by training them in this technique and, once active contraction becomes possible, pelvic floor exercises alone can be practiced.

Effective treatments are currently available for the treatment of urinary incontinence and have been demonstrated to be more beneficial than PFES. These include PFMT alone, behavioral training including bladder training and anti-cholinergic medication for urge incontinence. There is insufficient evidence from randomized clinical trials to conclude that PFES is as beneficial as these alternative therapies. In addition, PFES has not been shown to improve management of urinary incontinence in women when used as an adjunct to PFMT.

To date, PFES has not been shown to be as effective as behavioral or pharmacological therapy in the treatment of stress, urge and mixed incontinence in women.

## **RECOMMENDATION**

It is recommended that PFES does not meet CTAF criteria 2-5, for the treatment of urinary incontinence in women.

**The California Technology Assessment Forum approved the recommendation as stated.**

**October 20, 2004**

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