Biofeedback for pelvic floor muscle (PFM) dysfunction

Why is feedback important?
- Verbal instruction of PFM contraction has been shown to be ineffective in generating urethral closure force in 51% percent of patients (Bump 1991)
- And results in adverse bearing down in approximately 15% of patients (Bo 1988)
- Biofeedback: information about a bodily function that is not easily observed
- It can be visual, auditory or tactile
- Biofeedback is not a standalone treatment is an adjunct to pelvic floor muscle training (PFMT)

Forms of Biofeedback
- Simple: without specialized equipment, therapist's palpation internally, patient's palpation internally, observing with mirror externally
- Vaginal weight: slippage of the weight signals muscle relaxation and need for increased contraction
- Pressure: using change in air pressure to signal closure
- Electromyography (EMG): using microvolts released during muscle contraction to signal muscle activity
- Rehabilitative Ultrasound Imaging (RUSI) - visual feedback on elevation of muscle

Indications for biofeedback
- Underactive PFM - PFM weakness
- Stress urinary incontinence (SUI)
- Urge urinary incontinence (UUI)
- Mixed UI (MUI)
- Fecal incontinence (FI)
- Pelvic organ prolapse (POP) – cystocele, rectocele, uterine prolapse, rectal prolapse, perineal descent

Contraindications for vaginal probe in biofeedback
- Pregnancy, Immediate postpartum: within 6 weeks
- Immediate post-pelvic surgery: within 6 weeks
- During menstrual flow: bridging of signal
- Vaginal infection, recurrent thrush, or cystitis
- Impaired cognitive ability
- Dysuria or sever pelvic pain
Possible poor outcome for biofeedback
- Younger than 5 years old
- Cognitive limitation that make learning difficult
- Unable to see or hear the feedback

Method of biofeedback for pelvic floor dysfunction
Types of Simple Biofeedback performed by the therapist or patient
- Look: Using a mirror, watch the perineal body move into the body during a contraction. A correct contraction occurs with downward movement of the clitoris and inward movement of the anus.
- Palpate externally: Palpate the perineal body or anus during a contraction. It should move into the body. This can be done on the skin, underpants, or sometimes through thin pants in an exercise class.
- Palpate internally: place a finger into the vagina touching one side. Feel the contraction moving inward and upward. Vaginal palpation increases awareness of the muscle.
- Proprioceptive feedback: The most abundant sensory nerve fibers in the vagina carry proprioceptive information. Many women find they can identify and contract the pelvic floor muscles more effectively if they have something to contract around. There are various devices.

Pressure biofeedback
- Kegel first described PFM injury and its potential for rehabilitation using a pressure-sensitive device more than 50 years ago (Kegel 1948)
- Good reliability and reproducibility (Bo 1990, Hudley 2005)
- Keep patient position consistent: Head of bed, legs
- Placement of the air chamber: middle of the air chamber placed 3.5 cm inside the introitus (Bo 2005); must ensure constant placement of the sensor between and during training sessions
- Standardize inflation of the sensor: same volume
- Visualize or palpate for inward movement of the sensor to verify proper contraction. Bearing down with abdominals and use of accessory muscles: will result in increase in pressure reading without contraction of the PFM (Bo 2005)
- Large vaginal vault: contraction may create little pressure change despite maximal muscle recruitment
- Most pressure devices are not able to measure changes in resting pressure; not well-suited for overactive PFM
- Continent women had statistically significant higher maximal vaginal squeeze pressure when compared with incontinent women (Morkved 2004, Amaro 2005)
Rehabilitative Ultrasound Imaging RUSI

- PFM location, volume, and anatomy can be measured with ultrasound
- Mean PFM lift of 11.2 mm was visualized with the subjects positioned supine using real time ultrasound (Bo 2003)
- Used to measure the impact of PFM contraction on the urethra and bladder with transperineal and transabdominal approaches (Whittaker 2007)
- Can be used in supine and standing to training awareness of PFM elevation
- Continent women had statistically significant higher muscle thickness when compared with incontinent women (Morkved 2004)
- Several approaches have been described
  - Transabdominal - Suprapubically; sagittal or transverse placement of sound head
  - Transperineal / Translabial – placed on labia (Brækken 2009) Both squeeze and lift can be quantified during PFM contraction

Surface Electromyography (EMG or sEMG)

- Surface electrodes, vaginal or rectal probe
- Must be performed well for accurate test results. Biofeedback Certification International Alliance (BCIA)
- EMG recordings depict the summation of muscular electrical activity occurring in the muscle at rest and during contraction
- Surface EMG is superior to vaginal palpation in assessment of all variables except lift (Bo 2005)
- Correlation found between “PFM function as estimated by palpation” and EMG (Gunnarsson 1999)
- Interrater reliability and intraobserver reproducibility for EMG (Romanzi 1999)
- Test-retest reliability of EMG with significant clinical predictive validity (Glazer 1999).

Treatment protocols for all forms of biofeedback

- Based on strength training principles and evaluation results using components of PFMT
- Patient position
  - Anti-gravity: buttock up used with prolapse and very weak patient
  - Gravity eliminated: supine, most common starting position
  - Against gravity: sitting or standing, used with strong patients
- Work time - Based on evaluation results
- Rest time - At least equal to work, Weaker muscles need more rest
- Number of repetitions and sets
- Intensity - better to have a submaximal contraction of good quality than a maximal contraction with overpowering abdominals
- Block training is used initially – 5 second hold 10 times, 3 second hold 10 times
- Have patient observe contraction/release
  - Can they feel what they see? Have patient correlate PFM movement with biofeedback visual signal
  - Can they feel what they need to do to generate or release tension?
EMG Biofeedback Research for Underactive PFM

- Association for Applied Psychophysiology and Biofeedback created a rating for research in this field – treatment of female SUI was the only diagnosis with the highest rating – efficacious and specific (McKee 2008)
- NICE Guidelines and Dutch Guidelines (level 4) - biofeedback should be considered in order to aid motivation and adherence to therapy, and to increase awareness.
- Fitz (2012) - systematic review, no significant difference in adding EMG
- Herderschee (2011) – Cochrane review on biofeedback with PFM exercises for UI
  - 24 Trials including 1583 women included
  - “Women who received biofeedback were significantly more likely to report that their UI was cured or improved compared to those who received PFM training alone (risk ratio 0.75).
  - Further research is needed to determine if the benefit is related to the use of the device or simply the increase in professional exposure.
- Norton (2012) - Cochrane review of biofeedback in patients with FI. Limited, poor quality research with some evidence that biofeedback plus exercise is better than PFMT alone.

- Biofeedback predictors – two unpublished ICS abstracts (Schaefer 2010, Yoo 2010), one AUA abstract (Cheng 2009), and one published paper (Resnick 2013) attempted to identify predictors of EMG biofeedback success
  - Frequency of UI
    - Less than 1 UUI/day (Schaefer 2010)
    - Less than 2 UUI per week resulted in significantly better outcome with BF (Resnick 2013)
  - Presence of detrusor overactivity (DO) - was not a predictor (Schaefer 2010)
  - DO characteristics on urodynamics– more brisk and higher amplitude DO was a significant negative predictor. Stronger detrusor contractions predicted less success. (Schaefer 2010, Resnick 2013)
  - Multivalent analysis – increase in average tonic contraction of the PFM was an independent positive predictive factor for decreased UI with BF - OR 1.66 (Yoo 2010)
  - No patient characteristics limit success in biofeedback therapy (Yoo 2010)
  - Reduced UI was associated with: improvement in self-efficacy, perception of control, self-concept, self esteem, and decreasing anxiety. High depressive scores predicted worse outcome (Cheng 2009)

References for biofeedback


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Morkved S, Bo K, Fjortoft T. Effect of adding biofeedback to pelvic floor muscle training to treat urodynamic stress incontinence. Obstet Gynecol. 2002;100:730-739. RCT 1b


NICE Guideline - Urinary incontinence in women: the management of urinary incontinence in women - September 2013. National Collaborating Centre for Women’s and Children’s Health. UK


Yoo E, Kim y, Lee S. Factors predictive of response to biofeedback assisted pelvic floor muscle training for urinary incontinence. ICS abstract 724 – unpublished abstracts ICS 2010 Toronto CA
Electrical stimulation (ES) for PFM dysfunction

Indications for electrical stimulation
- Underactive PFM (weakness) - especially a very weak muscle (0/5 or 1/5) with poor awareness of PFM contraction
- Stress urinary incontinence (SUI)
- Urge urinary incontinence (UUI)
- Mixed UI (MUI)
- Fecal incontinence (FI)
- Pelvic organ prolapse (POP)

Contraindications for electrical stimulation
- On-demand pacemaker or history of arrhythmia - check with patient’s physician and pacemaker company, it is possible to use ES with some newer pacemakers
- Impaired cognitive function
- Vaginal infection, inflammation, or disease (for internal vaginal stimulation)
- Cancer - conflicting professional opinions - sensory stimulation will not increase blood flow and will not spread CA. Others do not use ES of any type with CA or radiation
- Atrophic vaginitis: do not use internal electrode

Considerations for vaginal and rectal ES treatment
- Pelvic organ prolapse (POP): grades 2 and 3, should make sure POP is up away from the electrode; advanced POP may not change significantly with ES
- Decreased sensation: potential for injury and may decrease effectiveness of stimulation

Possible adverse events
- Local vaginal, urethral, or anal irritation
- Bleeding
- Infection
- Pain and discomfort

Method of vaginal electrical stimulation
- There is a wide variability of parameters and protocols for ES reported in the literature
- It appears that some protocols may produce better outcomes than others; however, this has not been investigated yet (Berghmans 2005)
- Some practitioners suggest that having a patient actively contract PFM during ES may produce a better outcome; however, this has not been investigated yet
- Patient position
  - Supine: dorsal lithotomy is the most common position for treatment
  - Prolapse patients may need to be positioned with buttocks up on several pillows to move organs superior away from the electrode for better contact
# Internal NMES for Treatment of Urge and Underactive PFM

<table>
<thead>
<tr>
<th></th>
<th>Typical Urge Protocol</th>
<th>Typical Underactive PFM Protocol</th>
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</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
<td>5 to 20 HZ</td>
<td>5 to 50 Hz</td>
</tr>
<tr>
<td></td>
<td>12 Hz</td>
<td>50 Hz</td>
</tr>
<tr>
<td><strong>Pulse Duration (Width)</strong></td>
<td>200-350 usec</td>
<td>200-350 usec</td>
</tr>
<tr>
<td></td>
<td>250 usec</td>
<td>250 usec</td>
</tr>
<tr>
<td><strong>Wave Form</strong></td>
<td>Asymmetrical biphasic</td>
<td>Asymmetrical biphasic</td>
</tr>
<tr>
<td><strong>Amplitude (Intensity)</strong></td>
<td>To anal wink or patient tolerance</td>
<td>To anal wink or patient tolerance</td>
</tr>
<tr>
<td><strong>Duty Cycle</strong></td>
<td>5 seconds on</td>
<td>5 seconds on</td>
</tr>
<tr>
<td></td>
<td>5 to 10 seconds off</td>
<td>10 seconds on</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 seconds on</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>15 to 30 minutes</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td><strong>Frequency of RX</strong></td>
<td>3 to 5x/ week</td>
<td>3x/ week to twice per day</td>
</tr>
<tr>
<td><strong>Length of RX</strong></td>
<td>8 to 12 weeks to ongoing</td>
<td>8 weeks to on going</td>
</tr>
</tbody>
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**Organization guidelines for use of rectal and vaginal ES**

- Dutch guideline for treatment of SUI (Bernards 2013)
  - There is insufficient evidence that ES alone is an effective treatment for SUI (level 1)
  - Adding ES to PFM exercises does not offer additional benefit (level 1)
  - Might be useful to increase awareness of how to contract the PFM correctly in patients with decreased voluntary control

- European Association of Urology guidelines on UI (Lucas 2013)
  - Evidence is inconsistent for whether ES alone can improve UI (level 2)
  - ES is no better than antimuscarinics (level 1)

- NICE Royal College of Obstetrics and Gynecology Guidelines (NICE 2013)
  - Do not routinely use ES in the treatment of women with OAB.
  - Do not routinely use ES in combination with PFMT.
  - ES considered in women who cannot actively contract PFM.
  - Do not offer transcutaneous sacral nerve stimulation to treat OAB in women.
  - Do not offer transcutaneous posterior tibial nerve stimulation for OAB. There is insufficient evidence to recommend the use.
Evidence for ES

- Systematic review (Shamilyn 2008)
  - Active ES was not better than PFM exercises or sham ES
- Cochrane review - ES in men (Berghmans 2013)
  - Some evidence that ES has a short term effect of decreased UI (6 months) but no significant difference was seen at 12 months
  - No evidence that adding ES to PFM exercises increases benefit
  - 17% adverse events
- Overall, it appears that ES is better than no treatment for UI (Bo 1998; Berghmans 2000)
- Overall ES appears to have a 50% improvement rate (Brubaker 2000; Brubaker 1997; Wang 1997)
- SUI - PFM exercise vs ES vs vaginal weights vs no treatment: PFM exercises best, ES second best in decreased leaks and subjective improvements (Bo 1999)
- RCT anal ES for fecal incontinence (FI) (Norton 2005): 35 Hz vs 1 Hz, 5 seconds on, 5 seconds off, 300 microseconds pulse width 20 to 40 minutes for 8 weeks. Patients who used the ES for more than 10 hours had a better outcome. All patients reported a significant reduction in BM frequency and number of incontinent episodes.

Conclusions for use of vaginal and rectal stimulation

- Research is lacking and inconsistent in the use of ES in patients with PFM dysfunction
- No evidence that it should be offered routinely to all patients
- ES may be beneficial to
  - Enhance awareness of PFM contraction
  - Especially if PFM is very weak
  - If PFM exercises or medications have failed
- Should always be used with other conservative management techniques.

References for ES


**NICE Guideline** - Urinary incontinence in women: the management of urinary incontinence in women - September 2013. National Collaborating Centre for Women’s and Children’s Health. UK


**Vaginal weights**

Vaginal weights (VWs) were developed by Plevnik in 1985. Theoretically, the sensation of having the weight inserted into the vagina provides sensory proprioceptive feedback, prompting a PFM contraction to retain the weight. (Hay-Smith 2005)

**Indications for Use of VWs**
- Underactive PFM - mild weakness
- Urinary incontinence - SUI, UUI, MUI
- Poor kinesthetic awareness
- Incoordination of PFM during activities of daily living (ADLs)

**Contraindications for Use of VWs**
- Pregnancy
- Immediate postpartum: within 6 weeks
- Immediate post-pelvic surgery: within 6 weeks
- During menstrual flow: slips too much
- Vaginal infection, recurrent thrush, or cystitis
- Impaired cognitive ability
- Dysuria
- Suspected retention or obstruction
- Vaginal, pelvic, or genital disease
- IUD unless specifically recommended by physician
- Atrophic vaginitis
Possible Poor Outcomes with Use of VWs

- Very weak PFM (0/5 or 1/5)
- Large vaginal vault: weight tips to the side and becomes wedged
- Poor motivation
- Severe sensory deficit: can’t feel the weight slip
- PFM spasm or retention

Method

- The VW is inserted by the patient to a position above the PFM.
- When the muscle relaxes, the weight slips.
- Proprioceptive input prompts the patient to contract the PFM.
- Needle EMG studies show contraction of the PFM with weights inserted (Deindl 1995)
- Normal MMT (3/5 to 4/5): standing position with low exertional ADLs
  - Standing still
  - Motionless standing ADLs such as brushing teeth, showering, washing dishes
  - Increase the challenge by having patient move legs apart
  - Instruct the patient to weight shift in multiple directions
- Strong MMT (4/5 to 5/5): standing position with increases in intra-abdominal pressure and challenge functional coordination of the use of the PFM
  - Walking
  - Marching
  - Bowing
  - Transitions (sit to stand to stand squatting)
  - UE strengthening, Dynamic stabilization
  - Lifting
  - Coughing
  - Stair climbing
  - Jumping
  - Running

Frequency and Duration of Use: 10 to 15 minutes, One to two times per day
Progression of Training: Advancing weight, Advance activity

Cautions and Patient Instructions

- Empty bladder before treatment
- Remove tampon, pessary, or diaphragm before treatment
- Wash hands and VW before and after treatment with soap and water
- Do not use lubrication
- Be aware of VW becoming wedged
- Avoid frustration with short sessions of appropriate difficulty (ICI 2013, Dutch guidelines level 1)
- Single user device per manufacturer
- Variations in strength occur with time of day, fatigue, and hormonal fluctuation
- Patient have reported abdominal pain, vaginitis, and bleeding (ICI 2013, Dutch guidelines level 1)
Evidence for the Use of VWs in Practice

- Evidence from 4 RCT suggests VW are better than no treatment (ICI 2013)
- There was no statistical difference between VW and electrical stimulation for SUI; both treatments appear equally effective (Bo 1999; Olah 1990, ICI 2013, Dutch guidelines level 1)
- There is no statistically significant difference between VW with PFMT vs. PFMT alone (Cammu 1998, Pereira 2012, Pereira 2013, Dutch guidelines level 1)
- Combining VW with PFMT may be effective (Dutch guidelines level 3)

Cochrane review on vaginal weights (Herbison 2008)

- 17 studies randomized or quasi-randomized controlled trials comparing weighted vaginal weights with alternative treatments or no treatment (6 were abstract only)
- Use of VW is better than no active treatment
- VW “may” have similar effectiveness as PFMT and electrical stimulation
- Not enough evidence to demonstrate additional improvement with VW + PFMT treatment vs. PFMT alone.

References for VW


Moore K, et al. Adult conservative management, in Incontinence 5th ICI 2013


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