

Adjunctive treatments for pelvic floor dysfunction  
Conservative management for adult pelvic floor dysfunction: a physiotherapy  
approach - workshop #31  
Dr Beth Shelly PT, DPT, WCS, BCB PMD  
International Continence Society Annual Meeting  
October 21, 2014 Rio de Janeiro, Brazil

**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 (UII)
- Mixed UI (MUI)
- Fecal incontinence (FI)
- Pelvic organ prolapse (POP) – cytocele, rectocele, urterine 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**

- Multiple RCTs have failed to show a statistically significant difference between outcomes with and without EMG training for UI and FI (Morkved 2002, Taylor 1986, Burns 1993, Burns 1990, Berghmans 1996, Glavind 1996, Aksec 2003, Solomon 2003, Hirakawa 2013)
- 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**

Aksac B, Aki S, Karan A, et al. Biofeedback and pelvic floor exercises for the rehabilitation of urinary stress incontinence. *Gynecol Obstet Invest* 2003; 56(1):23-7.

Amaro JL, Moreira EC, Gameiro M, Pardovani CR. Pelvic floor muscle evaluation in incontinent patients. *Int Urogynecol J Pelvic Floor Dysfunct.* 2005;16:352-354.

Berghmans LMC, Fredericks CMA, deBie RA, et al. Efficacy of biofeedback, when included with pelvic floor muscle exercise treatment, for genuine stress incontinence. *Neurourol Urodyn.* 1996;15:37-52.

Bernards ATL, et al. Dutch guidelines for the physiotherapy treatment of stress urinary incontinence: an update. *Int J Urogyn* 2013.

Bo K, Larsen S, Oseid S et al. Knowledge about and ability to perform correct pelvic floor muscle exercise in women with stress urinary incontinence. *Neurourol and Urodynam*. 1988;7(3):261-262.

Bo K, Sherburn M. Evaluation of female pelvic floor muscle function and strength. *Phys Ther*. 2005; 85:269-282.

Bo K, Raastad R, Finckenhagen HB. Does the size of the vaginal probe affect measurement of pelvic floor muscle strength? *Acta Obstetricia et Gynecologica Scandinavica*. 2005; 84: 129-133.

Bo K. Pelvic floor muscle exercises for treatment of female stress urinary incontinence: 1. Reliability of vaginal pressure measurements of pelvic floor muscle strength. *Neurourol Urodyn*. 1990; 9:471-477.

Bo K. Pelvic floor muscle exercises for treatment of female stress urinary incontinence: 2. Validity of vaginal pressure measurements of pelvic floor muscle strength and the necessity of supplementary methods for control of correct contraction. *Neurourol Urodyn*. 1990; 9:479-487.

Bo K, Sherburn M, Allen T. Transabdominal ultrasound measurement of pelvic floor muscle activity when activated directly or via transversus abdominis muscle contraction. *Neurourol Urodyn*. 2003;22:582-588.

Brækken IH, Majida M, Engh ME, BØ K. Test-Retest Reliability of Pelvic Floor Muscle Contraction Measured by 4D Ultrasound. *Neurourology and Urodynamics* 28:68-73 2009

Bump RC, Hurt WG, Fantl A, Wyman JF. Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. *Am J of Obsteric and Gynecol*. 1991;165:322-329.

Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KL, Ory MG. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community dwelling women. *J Gerontol*. 1993;48:167-174. **RCT 1b**

Burns P, et al. Treatment of stress incontinence with pelvic floor exercise and biofeedback. *J Am Geriatr Soc*. 1990;38:341-344. **RCT 1b**

Cheng CI, et al. Psychological burden related to urge urinary incontinence predicts and its change correlates with therapeutic response to biofeedback in older women. #1868 Abstract from AUA meeting published in *J of Urol* 2009;181(4).

Fitz FF, et al. Biofeedback for the treatment of female pelvic floor muscle dysfunction: a systematic review and meta-analysis. *Int Urogynecol J* 2012;23:1495-1516.

Glavind K, Nohr S, Walter S. Biofeedback and physiology vs physiology alone in the treatment of genuine stress incontinence. *Int Urogynecol J*. 1996;7:339-343. **RCT 1b**

Glazer H. Pelvic floor muscle surface electromyography reliability and clinical predictive validity. *J Reprod Med*. 1999;44:779-782.

Gunnarsson M, Mattiasson A. Female stress, urge and mixed urinary incontinence are associated with chronic progressive pelvic floor/vaginal neuromuscular disorder: an investigation of 317 healthy and incontinence women using vaginal surface electromyography. *Neurourol Urodyn*. 1999;18:613-621.

Herderschee R, Hay-Smith EJ, Herbison GP, Roovers JP, Heineman MJ. Feedback of Biofeedback to augment pelvic floor muscle training for urinary incontinence. *Cochrane database syst rev* 2011;(7):CD009252

Hirakawa T, et al. Randomized controlled trial of pelvic floor muscle training with or without biofeedback for urinary incontinence. *Int Urogynecol J* 2013;24:1347-1354.

Hudley AF, Wu JM, Visco AG. A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. *Am J Obstet Gynecol*. 2005;192:1583-1591

Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. *Am J Obstet Gynecol*. 1948; 56:238. **Expert opinion 5**

McKee MG. Biofeedback: an overview in the context of heart-brain medicine. *Cleveland clinic J of Med* 2008;75(2):S31-S34.

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**

Morkved S, Salvesen KA Bo K, Eik-Nes S. Pelvic floor muscle strength and thickness in continent and incontinent nulliparous pregnant women *Int Urogynecol J*. 2004;15:384–390

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

Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev* 2012 Jul 11;7:CD002111.

Resnick NM, et al. What predicts and what mediates the response of urge urinary incontinence to biofeedback? *Neurourol and Urodynam* 2013;32:408-415.

Romanzi LJ, et al Simple test of pelvic muscle contraction during pelvic exam: correlation to surface electromyography. *Neurourol Urodyn*. 1999;18:603-612.

Schaefer W, Griffiths D, Tadic S, Perera S, Resnick N. Mechanism of biofeedback therapy for urgency incontinence. ICS abstract 729 – unpublished abstracts ICS meeting 2010 Toronto CA

Solomon MJ, et al. Randomized controlled trial of biofeedback with anal manometry, transanal ultrasound, or pelvic floor retraining with digital guidance alone in the treatment of mild to moderate fecal incontinence. *Dis Colon Rectum*. 2003;46(6):703-710.

Whittaker JL, Thompson JA, Teyhen DS, Hodges P. Rehabilitative ultrasound imaging of pelvic floor muscle function. *Journal of Orthopaedic & Sports Physical Therapy* 37(8):487-98, 2007 Aug.

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 (UII)
- 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 pace makers
- 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

	Typical Urge Protocol	Typical Underactive PFM Protocol
<b>Frequency</b>	5 to 20 HZ 12 Hz	5 to 50 Hz 50 Hz
<b>Pulse Duration (Width)</b>	200-350 usec 250 usec	200-350 usec 250 usec
<b>Wave Form</b>	Asymmetrical biphasic	Asymmetrical biphasic
<b>Amplitude (Intensity)</b>	To anal wink or patient tolerance	To anal wink or patient tolerance
<b>Duty Cycle</b>	5 seconds on 5 to 10 seconds off	5 seconds on 10 seconds off  10 seconds on 10 seconds off
<b>Duration</b>	15 to 30 minutes	15 to 30 minutes
<b>Frequency of RX</b>	3 to 5x/ week	3x/ week to twice per day
<b>Length of RX</b>	8 to 12 weeks to ongoing	8 weeks to on going

### 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

Berghmans LC, et al. B4: physical therapies: electrical stimulation. In: Abrams P, Cardozo L, Khoury S, Wein A, eds. *Incontinence: 3rd International Consultation on Incontinence*. Plymouth, UK: Health Publications Ltd; 2005:chapter 15. SR1a

Berghmans LC, Hendriks HJ, De Bie RA, Van Waalwijk Van Dorn ES, Bo K, van Kerrebroeck PE. Conservative treatment of urge urinary incontinence in women: a systematic review of randomized clinical trials. *BJU Int*. 2000;85:254-263. SR 1a

Berghmans B, et al. Electrical stimulation with non implanted electrodes for urinary incontinence in men. Cochrane review 2013

Bernards ATL, et al. Dutch guidelines for the physiotherapy treatment of stress urinary incontinence: an update. *Int J Urogyn* 2013.

Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress urinary incontinence. *BMJ*. 1999;318:487-493. RCT 1b

Bo K. Effect of electrical stimulation on stress and urge urinary incontinence. *Acta Obstet Gynecol Scand.* 1998;77(suppl 168):3-11. SR 1a

Brubaker L, Benson T, Bent A, Clark A, Shott S. Transvaginal electrical stimulation for female urinary incontinence. *Am J Obstet Gynecol.* 1997;177:536-540. RCT 1b

Brubaker L. Electrical stimulation in overactive bladder. *Urology.* 2000;55(suppl 5A):17-23.

Norton C, Gibbs A, Kamm M. Randomized controlled trial of anal electrical stimulation for fecal incontinence. *Dis Colon Rectum.* 2005;49:190-196. RCT 1b

Lucas MG, et al. Guidelines on urinary incontinence. European association of urology, 2013.

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

Shamliyn TA, et al. Systematic review: randomized, controlled trials of nonsurgical treatments for UI in women. *Ann Intern Med* 2008;148.

Wang AC, Ya-Ying W, Min-Chi C. Single blind, randomized trial of pelvic floor muscle training, biofeedback, assisted pelvic floor muscle training, electrical stimulation in the management of overactive bladder. *Urology.* 2004;63:61-66. RCT 1b

## **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, UII, 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

Bernards ATL, et al. Dutch guidelines for the physiotherapy treatment of stress urinary incontinence: an update. *Int J Urogyn* 2013.

Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ*. 1999;318:487-493. **RCT 1b**

Cammu H, Van Nylén M. Pelvic floor exercises versus vaginal weight cones in genuine stress incontinence. *Eur J Obstet Gynecol Reprod Biol*. 1998;77:89-93. **RCT 1b**

Deindl F, Schussler B, Vodusek D, Hesse U. Neurophysiologic effect of vaginal cone application in continent and urinary stress incontinent women. *Int Urogynecol J Pelvic Dysfunct*. 1995;6:204-208.

Hay-Smith EC, Bo K, Berghmans LM, et al. Pelvic floor muscle training for urinary incontinence in women [Cochrane review]. In: *The Cochrane Review Library*. Chichester, UK: John Wiley and Sons Ltd; 2004:issue 2. **CR 1a**

Herbison, P; Dean, N. Weighted vaginal cones for urinary incontinence. *The Cochrane Review Library*. Cochrane Database of Systematic Reviews. 2, 2008.

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

Olah KS, Bridges N, Denning J, Farrar DJ. The conservative management of patients with symptoms of stress incontinence: a randomized prospective study comparing weighted vaginal cones and interferential therapy. *Am J Obstet Gynecol*. 1990;162:87-92. **RCT 1b**

Pereira VS, et al. Vaginal cone for postmenopausal women with stress urinary incontinence: randomized controlled trial. *Climacteric* 2012;15(1):45-51.

Pereira VS, et al. Long-Term Effects of Pelvic Floor Muscle Training With Vaginal Cone in Post-Menopausal Women With Urinary Incontinence: A Randomized Controlled Trial. *Neurourology and Urodynamics* 32:48–52 (2013).