## **Case Study**

# **Pelvic Floor Biofeedback via a Smart Phone App for Treatment Of Stress Urinary Incontinence**

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#### **Case Presentation**

A 37-year-old woman, K.S., presented to a Midwest academic urogynecology clinic for treatment of her symptoms of stress urinary incontinence (SUI). She was referred by a friend who had successfully completed a comprehensive pelvic floor rehabilitation program at this clinic for similar symptoms. This type of program offers the standard of care for women with symptoms of urinary incontinence (UI) and incorporates biofeedback, pelvic muscle training and behavior modification (Starr et al., 2013).

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Biofeedback can be useful for treatment of stress urinary incontinence. Many women have difficulty isolating their pelvic floor muscles and adhering to a daily exercise regimen. This case study highlights a woman's experience using PeriCoach<sup>®</sup>, a home biofeedback device that assists women in strengthening their pelvic floor muscles through Bluetooth<sup>™</sup> technology using a smartphone.

Key Words: Stress urinary incontinence, biofeedback, pelvic floor muscle training, PeriCoach<sup>®</sup>, smart phone app.

K.S. stated that her main complaint was "wetting my pants while running." She was also bothered by leaking urine several times a day when talking, coughing, laughing, sneezing, lifting, and other forms of exercise. Her symptoms started after the birth of her first baby almost five years ago. She reported voiding every 3 to 4 hours during the day and did not get up in the night to void. She was particularly frustrated because she felt she could improve with Kegel exercises, but she had difficulty remembering to perform them every day. On an average day she drank 64 to 80 oz of water and 1 to 2 cups of coffee.

She reported almost daily firm bowel movements and strained to pass stool. She denied symptoms of anal incontinence. She denied symptoms of pelvic organ prolapse, such as a bulge or pressure in the vagina. She reported being sexually active without problems. Her medical history was negative other than a diagnosis of plantar fasciitis. Her obstetrical history was significant for three vaginal deliveries, with a maximum birth weight of 6 pounds, 12 ounces. She reported labors of less than 3 hours and recalls a second or third degree obstetrical injury with her first delivery.

K.S. enjoys an active lifestyle and spending time with her family. She is married with three children, 18 months, 3 years, and 4.5 years of age. Her family resides on a farm where they raise cattle and farm hay. She has a bachelor's degree, and both she and her husband work full-time jobs. A typical day for K.S. is waking at 5:00 a.m. and performing an hour of cardio exercise on a treadmill or elliptical machine. She then completes the morning chores on the farm, gets her children ready for the day, and is off to work. She describes her lifestyle as "very physical." She expressed frustration with her UI

symptoms and her inability to adhere to a daily pelvic floor muscles (PFM) exercise regimen.

#### **Clinical Interaction**

## Physical Examination And Office Testing

K.S. was evaluated by a nurse practitioner who specializes in female pelvic floor dysfunction. A pelvic examination was performed. Post-void residual measured 30 cc. Urinalysis was negative for blood, leukocytes and nitrites. The pelvic organ prolapse examination revealed mild asymptomatic cystocele and uterine prolapse, and good support of the posterior vaginal compartment. Significant urethral hypermobility was noted. UI was evident with Valsalva maneuver. Vaginal tissue was well-estrogenized. Bilateral digital examination of levator ani muscles revealed normal tone and the patient was able to isolate her PFM with some coaching. Her PFM strength measured 2 (weak) per the modified Oxford Grading System 0-5 (Laycock, 1994). Rectal examination revealed normal sphincter tone.

The patient was diagnosed with Stage I cystocele, Stage I uterine prolapse SUI, defecatory dysfunction, and pelvic muscle weakness. She was given options for treatment, which included PFM rehabilitation, a pessary, or surgery. She desired nonsurgical intervention and completed a 5minute session of pelvic muscle biofeedback with the use of a vaginal EMG probe to monitor levator ani muscles and an EMG electrode patch to monitor the rectus abdominus/accessory muscle. Her PFM resting tone measured 0.5 uv (normal range 0 to 2 uv). She required coaching to decrease use of her accessory/abdominal muscles during contractions. She then underwent a 30-minute session of vaginal electrogalvanic stimulation (50 Hz, 5 seconds work, 5 seconds rest) to assist in identification and isolation of PFM. K.S. was advised to take a heaping teaspoon of psyllium fiber daily to Figure 1. PeriCoach<sup>®</sup> Device and Smart Phone Displaying Biofeedback Screen



**Source:** Used with permission from Analytica Ltd.

facilitate more complete rectal emptying. She was given a PFM exercise regimen to perform 4 times per day (contract 5 seconds, relax 5 seconds, repeat 10 times) and a follow-up appointment in 4 weeks.

Upon her 4-week follow-up appointment, she reported daily bowel movements with regular use of psyllium fiber. She reported only mild improvement in her SUI symptoms and was having difficulty adhering to PFM exercises daily. Due to her continued SUI symptoms and lack of adherence to the PFM exercises, she was offered an opportunity to take part in an Institution Review Board-approved research study currently being conducted at this academic outpatient clinic. She met the inclusion criteria (SUI and access to a smartphone or tablet) for this usability study on biofeedback device called а PeriCoach<sup>®</sup> (Analytica, Brisbane OLD 4001, Australia).

The PeriCoach system is a PFM home biofeedback device that provides real-time audiovisual feedback and monitoring of PFM exercise performance using Bluetooth<sup>™</sup> technology (see Figure 1). The device is approved by the U.S. Food and Drug Administration (FDA) and available in the U.S. with a prescription. It is designed for vaginal insertion to detect pubococcygeus and puborectalis muscle activity. The PeriCoach app can give users reminders and encouragement messages, which coupled with biofeedback, helps with compliance with PFM exercises.

### **Research Study**

K.S. consented to take part in this clinical research trial approved by the Institution Review Board of the University of Health Science Missouri. The study was designed to evaluate patient/clinician usability of the PeriCoach® system, PFM exercise adherence, changes in pelvic muscle force and tone, symptom improvement, and quality of life (QOL). Five women scheduled at this Midwest urogynecology outpatient clinic reporting mild to moderate symptoms of SUI with daily access to a smartphone or tablet were enrolled and instructed to use the device twice daily.

Subjects completed two validated instruments, the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7), at initial treatment, 2 weeks, 4 weeks, and 8 weeks. Subject and clinician usability questionnaires were completed at the 8-week visit. The PFDI-20 and PFIQ-7 questionnaires are considered the most reliable and rigorous instruments available in assessing life impact and QOL of women with symptoms of pelvic floor dysfunction (PFD), including UI, POP, and anal incontinence. The PFIQ-7 is the only questionnaire that assesses life impact in women with pelvic floor disorders. Both are easy to use in clinical and research settings, thereby decreasing subject burden (Barber et al., 2011).

The PFDI-20 is both a symptom inventory and a measure of the degree of bother and distress (QOL) caused by pelvic floor symptoms. It includes 20 questions and three scales. Each of the three scales are scored from 0 (least distress) to 100 (greatest distress). The overall summary score ranges from 0 to 300. The three distress inventory scales include:

urinary – 6 questions, POP – 6 questions, and colorectal – 8 questions (Barber, Walters, & Bump, 2005). The PFDI-20 has good testretest reliability and strong construct validity (Barber et al., 2005).

The PFIQ-7 is a shortened version of the PFIQ and is used to assess life impact in women with pelvic floor disorders. It consists of three scales of seven questions each taken from the Urinary Impact Questionnaire, the POP Impact Questionnaire, and the Colorectal-Anal Impact Questionnaire. The three scales are scored from 0 (least impact) to 100 (greatest impact) and an overall summary score (0 to 300). Each of the three scales correlates highly with their long forms and demonstrates construct validity; it demonstrates a significant association with appropriate measures of symptom severity and pelvic floor diagnosis (Barber et al., 2005).

#### **Results of Clinical** Interaction

K.S. was an excellent candidate for the PeriCoach device due to her diagnosis of SUI and difficulty with PFM exercise adherence. Study results demonstrated that with use of the PeriCoach, she was able to remember to perform PFM exercises twice a day and her symptoms markedly improved. At her 8-week follow up, she reported significant improvement in her SUI symptoms. She was able to complete her daily cardio workout and chores on the farm without leaking urine. She did report a rare occurrence of UI when sneezing or coughing with a full bladder, but was otherwise dry. She was very satisfied with her outcome.

As part of the PeriCoach System, patients may share exercise data with their provider. Through the PeriCoach clinician online portal, this author was able to track K.S.'s exercise adherence and change in PFM force. She was diligent with use of PeriCoach twice a day, and her PFM resting tone improved after 8 weeks. Figure 2 depicts her improved tone and pelvic muscle force during the final 6 weeks of



Figure 2. Change in Resting Tone (Red) and Squeeze Force (Blue)

Figure 3. Distress Score at Initiation of Treatment – 2, 4, and 8 Weeks



exercise. The resting tone displayed is derived from the sensor data collected by the PeriCoach as an average minimum reading during rest for all sensors over a period of 6 weeks. Her PFDI-20 (see Figure 3) and PFIQ-7 (see Figure 4) questionnaire results revealed significant improvement in all pelvic distress scales. PFDI-20 overall score went from 195.84 to 15.63, and the UI distress score went from 66.67 to 8.33, indicating 80% and 125% improvement respectively in QOL. The PFIQ-7 overall score started at 66.67 and decreased to 4.76, and specific UI score went from 38.1 to 4.76, revealing 71% and 125% improvement in impact of symptoms on QOL, respectively. These findings indicate a significant improvement in QOL due to PFM exercise adherence with use of PeriCoach for 8 weeks.



#### **Clinical Implications**

UI is a common condition experienced by 1 in 3 women, and PFM exercise have been shown to be an effective first-line treatment (Berghmans et al., 1998; Bø, Talseth, & Holme, 1999; Fantyl et al., 1996; Henalla, Hutchins, Robinson, & MacVicar, 1989; Lagro-Janssen, Debruyne, Smiths, & Van Weel, 1992; Wilson, Bø, & Nygaard, 2002). There is much scientific evidence to show that over 30% of women have difficulty isolating their PFMs (Benvenuti et al., 1987; Bø, Larsen, & Oseid, 1988; Bump, Hurt, Fantly, & Syman, 1991; Hesse, Schussler, & Frimberger, 1990; Kegel, 1948). An even greater number of women have trouble adhering to a daily PFM exercise regimen (Bø & Hilde, 2013).

Biofeedback can be a vital component of a behavioral pro-(Hay-Smith, gram for SUI Henderschee, Dumoulin, & Herbison, 2012; Newman & Wein, 2013). It is a technique in which physiological activity (neuromuscular and autonomic activity) is monitored and conveyed back to the patient as visual or acoustic signals (Newman & Wein, 2009). It provides immediate feedback to an individual about normal body processes of which they may be unaware. The success of biofeedback for PFM strengthening is based on a learning process known as "operant conditioning." The governing principal is that when any behavior is reinforced, such as a muscle contraction, its likelihood of being repeated, and perfection increases (Newman, 2014). Use of a home biofeedback device can improve patient PFM force and adherence to a home exercise program. K.S. found PeriCoach to be comfortable and easy to use. She continues to report ongoing symptom control with compliance to a daily PFM exercise regimen.

#### Conclusion

Many women with SUI do not have access to a clinic-based biofeedback program. They may find home biofeedback more cost effective and easier to incorporate into their busy lifestyle. Peri-Coach is easy to use and provides a guided and personalized exercise regimen to help strengthen PFMs, and decrease symptoms of SUI. The app can be programmed to send reminders to a smartphone or tablet, which can also assist in adherence. It is an affordable and effective non-surgical option for women with symptoms of SUI.

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