ANALYTICA

CEO Presentation to Analytica Annual General Meeting

26 November 2020

Forward-Looking Statements

This presentation contains forward-looking statements that involve risks and uncertainties.

Although we believe that the expectations reflected in the forward looking statements are reasonable at this time, Analytica can give no assurance that these expectations will prove to be correct.

Actual results could differ materially from those anticipated.

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Strategy

Plan A – Global licensing / sale

Plan B – DIY manufacturing with regional distribution partners

- Each Country or Region adds overhead – Regulatory, logistics, IT and manufacturing.
- Manufacturing and post-market needs to be more closely controlled – ALT needs to take on more responsibility in-house.
  - Requires ALT to be QSR and ISO 13485 compliant.
  - Needs changes to manufacturing processes

Regional Distributors

We are targeting existing, proven regional distributors in the personal medical device and/or urogynaecological space.

The distributors will provide/assist with:

- Local regulatory clearances – generally 6-18 months
- Translations of websites, software, documentation content
- Logistics and customs clearance.
- Adapting / creating marketing materiel and techniques suited to local market, healthcare systems and customs.

- Middle East underway
- Investigating others – hampered by COVID-19

Manufacturing

- COGS reduction
- Redesign of electronics
  - Some components were going out-of-life
  - Cheaper and more powerful components now available
  - Clean up and simplify design
- Streamline supply chain.
- Update Manufacturing Test System
- Absorb more manufacturing responsibility in-house.
- Create a manufacturing process that can be duplicated and scaled.

Regulatory

- Working on additional regional clearances in partnership with distributors
- US QSR-compliant quality system operational.
- ISO 13485 compliant, but has not yet been certified. Backlog of Notified Bodies (i.e. auditors/certifiers) due to European Medical Device Regulation (MDR)

Clinical Evidence

Home Biofeedback Versus Physical Therapy for Stress Urinary Incontinence: A Randomized Trial

- Independent Randomised Controlled Clinical Trial 2019
- De Winter (Barnes) et al, University of New Mexico.
- Published in Female Pelvic Medicine & Reconstructive Surgery, the Official Journal of the American Urogynecologic Society (AUGS)
- PeriCoach treatment is non-inferior to supervised pelvic floor physical therapy (PFPT) for the treatment of stress urinary incontinence in women.

ORIGINAL ARTICLE

Home Biofeedback Versus Physical Therapy for Stress Urinary Incontinence: A Randomized Trial

Kara Lauren Barnes, MD, Sara Cichowski, MD, FACOG, FPMRS,† Yuko M. Komesu, MD, FACOG, FPMRS,* Peter C. Jeppson, MD, FACOG, FASC, FPMRS,* Brenna McGuire, MD,* Cara S. Nimeaggio, MD, FPMRS,* and Gena C. Dunivan, MD, FACOG, FPMRS**

Objective: The aim of the study was to assess whether home biofeedback is noninferior to supervised, pelvic floor physical therapy (PFPT) for the treatment of stress urinary incontinence (SUI) in women.

Methods: The study used a randomized controlled noninferiority trial to compare a home biofeedback device with PFPT. Women older than 18 years with SUI and no history of a prior incontinence surgery or PFPT were eligible. Forty-two participants were required to determine noninferiority for the primary outcome, improvement in quality of life as measured by the International Consultation on Incontinence Questionnaire Short Form. The noninferiority margin was 4 points. Secondary outcomes included sexual function, overactive bladder symptoms, and patient impression of improvement.

Results: From June 2018 to October 2019, 51 women with SUI were recruited (27 biofeedback, 27 PFPT) and 43 (21 biofeedback, 22 PFPT) completed follow-up. The groups had comparable baseline characteristics. For the primary outcome of change in mean International Consultation on Incontinence Questionnaire–Short Form scores (where lower scores indicate less incontinence), home biofeedback was found to be noninferior to PFPT with a mean decrease from baseline of −3.95 (95% confidence interval [CI] = −2.21 to −5.70) in the home biofeedback group versus −4.73 (95% CI = −3.21 to −6.25) and −3.95 (95% CI = −2.21 to −5.70) in the PFPT group ($P = 0.008$). The PFPT group showed more improvement in overactive bladder symptoms, but not in incontinence severity without difference in sexual function.

Conclusions: Home biofeedback was noninferior to PFPT for the primary treatment of SUI in women at 3 months. These results support the use of personal biofeedback devices for the treatment of SUI.

Clinical Trial Registration: ClinicalTrials.gov, http://www.clinicaltrials.gov, NCT03641687.

Key Words: stress urinary incontinence, pelvic floor physical therapy, home biofeedback

(*Female Pelvic Med Reconstr Surg* 2020;00: 00–00)

Urinary incontinence is a costly, widespread problem affecting 10%-30% of all women.[1] Most urinary incontinence is attributed to stress urinary incontinence (SUI) or mixed urinary incontinence (MUI).[2] Stress urinary incontinence is the involuntary loss of urine with physical exertion or with sneezing or coughing, whereas MUI includes both SUI and urgency leading to loss of urine.[3] Psychologically, SUI can cause isolation, embarrassment, and impaired sexual relationships.[4]

Pelvic floor physical therapy (PFPT), the recommended first-line therapy for SUI, is the most cost-effective nonsurgical treatment and is often augmented using biofeedback.[5,6] A 2011 Cochrane review found that participants receiving biofeedback were more likely to report cured or improved urinary incontinence compared with PFPT alone.[7] However, biofeedback alone without PFPT has not been extensively studied. Several personal biofeedback devices have been cleared by the U.S. Food and Drug Administration and approved for sale over the counter to treat SUI.[8] Home therapy may offer more opportunities to treat women unable to access PFPT because of cost or distance from providers. The PeriCoach device (home biofeedback) uses a silicone-coated vaginal pressure-rate to provide instant feedback via a smartphone Bluetooth application (app) to guide women in performing pelvic floor exercises.[9] The secure smartphone app provides graphical biofeedback of contraction force over time, and women can use this information to better engage the correct muscles. Using the gamified programs in the smartphone app, women are able to achieve levels of proficiency based on the strength and duration of their muscle contractions. Early evidence from an unpublished multicenter randomized controlled trial completed in Australia suggests that this device may be effective for the treatment of SUI and MUI.[10] This device was chosen for study because it is available over the counter for $299, available in all states, and is one of the few vaginal biofeedback devices to have obtained U.S. Food and Drug Administration 510(k) clearance for the treatment of stress, urge, and mixed incontinence in women.[9] Although many women purchase these devices, efficacy in treating SUI is not well established.

The primary aim of this study was to evaluate whether home biofeedback is noninferior to traditional PFPT for the treatment of SUI. Secondary outcomes included sexual function, overactive bladder (OAB) symptoms, and patient impression of overall improvement.

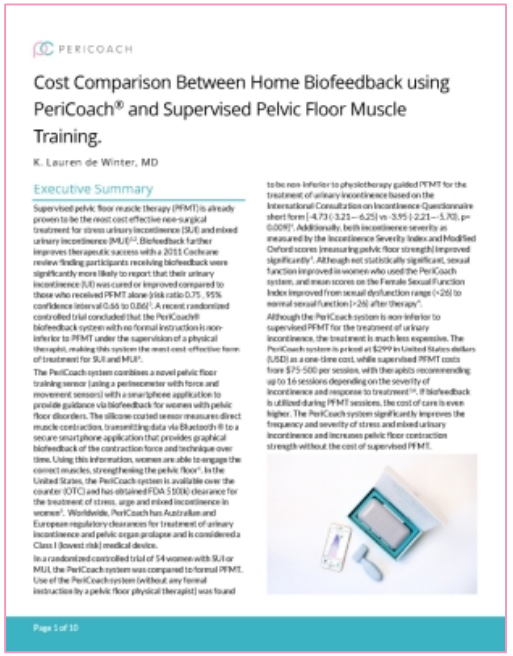
MATERIALS AND METHODS

We designed a 2-armed, randomized controlled noninferiority trial (PFPT vs home biofeedback). Patients with bothersome SUI or MUI with stress predominant symptoms were recruited from the University of New Mexico (UNM) urogynecology affiliated clinics in Albuquerque, New Mexico, from June 2018 to October 2019. Before enrollment, the study was approved by the UNM Human Research Protections Office (HRPO 18-110) and was registered on clinicaltrials.gov (NCT03641687). Female participants were eligible for recruitment if they were at least 18 years of age, owned a smartphone, and desired nonsurgical treatment for their SUI. Diagnosis of SUI was made by patient report of involuntary leakage with physical exertion, sneezing,

Health Economics

- De Winter (Barnes) looked into costs associated with Using PeriCoach vs supervised PFPT
- Whitepaper "*Cost Comparison Between Home Biofeedback using PeriCoach® and Supervised Pelvic Floor Muscle Training*."
- Conclusion:

Use of the PeriCoach system significantly improves the quality of life with women with SUI and MUI and is non-inferior to the current standard of care. The system costs significantly less to both patients and payers for similar treatment success and may prevent or delay women from needing expensive surgical treatments.


PERICOACH

Cost Comparison Between Home Biofeedback using PeriCoach® and Supervised Pelvic Floor Muscle Training.

K. Lauren de Winter, MD

Executive Summary

- Example:

PeriCoach = USD$299 versus PFPT > USD$900

Public Health

- UI and POP are public health issues
- Compare with smoking, seatbelts, skin cancer, obesity, fitness
- Governments and health insurers pay $millions to try to make people change behaviour now (inconvenience themselves) for future benefits or cost savings to themselves and community.
- Pelvic floor health requires exercise now to reduce surgeries, delay nursing home admissions, and improve productivity and mental health.
- Governments and Insurers are the natural customer for PeriCoach.
- Looking to health systems and payers domestically (State and Federal) and internationally with strong Clinical Evidence and Health Economics in hand.
- New mums (rehabilitation / preventative) and post-menopausal targets