

# PFD Week Abstracts Show Leva's Long-Term Treatment Value for Female Urinary Incontinence Plus New Data for Other Pelvic Floor Disorders

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24-month data show UI symptom relief is durable

Early data show symptom relief for pelvic organ prolapse

PORTLAND, Ore.--(BUSINESS WIRE)-- **AUGS PFD Week 2023**— Axena Health, Inc. (Axena Health), a medical device company focused on female pelvic health, commends leading researchers in women's health, who presented data showing that urinary incontinence (UI) symptom relief is durable for two-years following eight-weeks of treatment with the Leva® Pelvic Health System. These researchers also presented data showing that the Leva System improved symptoms of early-stage pelvic organ prolapse, a pelvic floor disorder in which one or more of the pelvic organs drop or press into or out of the vagina due to a weak pelvic floor. The Leva System is a non-drug, non-surgical treatment that helps women strengthen their pelvic floor at home, on their own schedule, by guiding correct and consistent pelvic floor muscle training (PFMT). The researchers presented their data in two abstracts during PFD Week 2023, the American Urogynecologic Society's (AUGS) annual scientific meeting held in Portland, Ore. Oct. 4-6, 2023.

The abstract, "Digital Therapeutic Device for Urinary Incontinence: An 18- and 24-month Follow-up of a Randomized Controlled Trial," showed that the Leva System provided durable and significantly greater improvement in stress and mixed UI symptoms compared to a home-based program of PFMT alone, regardless of whether women continued Leva use beyond the eight-week treatment period. The authors, who are widely recognized for their expertise in women's pelvic floor health, include Milena M. Weinstein, MD of Massachusetts General Hospital, Harvard Medical School, Gena Dunivan, MD of the University of Alabama, Noelani Guaderrama, MD of Kaiser

Southern California and Holly E. Richter, PhD, MD of the University of Alabama. The abstract is significant for several reasons:

- It provides long-term evidence for a non-surgical UI intervention, contributing to overall knowledge of how women can achieve durable symptom relief from what is often a long-term, progressive condition.
- It extends the findings of a randomized controlled superiority trial (RCT), published in **Obstetrics and Gynecology** (The Green Journal) in 2022, which showed the Leva System was statistically and clinically superior to Kegel exercises alone for stress and mixed UI symptom improvement and a prior longitudinal analysis showing that these improvements last 12 months, even without ongoing use of the Leva System. The **Green Journal** published the 12-month longitudinal analysis in January 2023.
- The authors conclude that for women choosing first-line, at-home care for stress or mixed UI, a motion-based device should be considered to optimize results.

"It's both exemplary and rare for a medical device that treats UI to have two-year longitudinal follow up to a randomized controlled trial," said Samantha Pulliam, chief medical officer for Axena Health. "We do, and it provides powerful validation of the Leva Pelvic Health System's treatment value for women. Now, data show UI symptom relief lasts for 24 months. We remain exceedingly grateful to the researchers who are building a compendium of data that support women's access to drug-free, surgery-free treatment for urinary incontinence that reflects conservative, first-line treatment guidelines."

Updated **prevalence data** show 61.8 percent of adult women live with UI, a progressive condition that can negatively impact women's quality of life and impose enormous physical, psychological, and economic burdens. Clinical guidelines recommend PFMT, as first-line treatment for UI, but achieving effective, consistent results is challenging. The Leva System makes PFMT accessible by guiding women through their treatment. The U.S. Food and Drug Administration (FDA) cleared the Leva System in 2019 for the treatment of stress, mixed and mild-to-moderate urgency UI. On June 20, 2023, Axena Health introduced the Leva System **for the treatment of chronic fecal incontinence** in women following **FDA clearance in 2022** and **Breakthrough Device Designation in 2021**. The new product introduction supports a single treatment option for the 20 percent of women with both UI and FI.

"Drs. Weinstein, Dunivan, Guaderrama and Richter are among the most respected clinician-researchers in their field, and they've amassed the highest quality evidence supporting the treatment value of the Leva Pelvic Health System," said Axena Health CEO Eileen Maus. "With more than half of adult women living with urinary incontinence, the quality of data supporting Leva's effectiveness and strong clinician demand for better treatment options, it's now egregious for insurance companies to deny coverage. Incontinence for many is a progressive condition that leads to adult diapers and older women entering nursing homes prematurely. Leva makes FDA-cleared, clinically proven, first-line treatment for incontinence accessible."

In the abstract, “Impact of pelvic floor muscle training with and without a motion-based device on pelvic floor disorder symptoms,” the authors analyzed the data from the original UI RCT to evaluate PFMT’s impact on symptoms of fecal incontinence (FI) and pelvic organ prolapse (POP). The analysis shows that PMFT treatment with the Leva System resulted in FI and POP symptom improvement. The research also showed that women with multiple pelvic floor disorders had more severe UI symptoms than women with UI only. The Leva System is not FDA cleared for the treatment of POP.

## About the Leva® Pelvic Health System

The Leva® Pelvic Health System is a prescription medical device available in the United States that offers an innovative, non-invasive, medication-free way for women to train and strengthen their pelvic floor muscles—at home in just five minutes a day—to treat urinary incontinence (UI) and chronic fecal incontinence (FI). Combining a small FDA-cleared vaginal motion sensor and integrated software, the Leva System offers precise visualization of pelvic movement in real-time, enables progress tracking and allows active clinician involvement, all of which support women’s success. Recognizing that level-one evidence shows pelvic floor muscle training is most effective when performed under the supervision of a skilled healthcare provider, the Leva System is available by prescription only, allowing physicians the opportunity to treat UI and chronic FI on a broad scale and with continued involvement in patient success. The Leva System is the first femtech product included in the Digital Therapeutics Alliance product library and has multiple clinical trials and published data from globally recognized medical centers supporting its efficacy in treating UI, including two studies in Obstetrics and Gynecology (The Green Journal), the official publication of the American College of Obstetricians and Gynecologists (ACOG).

## About Axena Health

Axena Health, Inc. is a women-led company dedicated to improving the lives of women with pelvic floor disorders. Axena Health’s flagship product, the Leva® Pelvic Health System, offers a novel, effective, first-line treatment for urinary incontinence (UI) and chronic fecal incontinence (FI), underreported conditions affecting over 78 million and 12 million women in the U.S. alone. Axena Health's technology enables non-invasive, drug-free treatment via precise visualization of movement in real time during pelvic floor muscle training, while monitoring usage and progress. For more information, please visit [www.axenahealth.com](http://www.axenahealth.com) or [www.levatherapy.com](http://www.levatherapy.com), follow Axena Health on **LinkedIn** and follow Leva Pelvic Health System on **Instagram** and **TikTok**.

## Important Indication and Other Information for the Leva® Pelvic Health System

The Leva® Pelvic Health System is intended for (1) strengthening of pelvic floor muscles, (2) rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed, and mild to moderate urgency urinary

incontinence (including overactive bladder) in women and (3) rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence ( $\geq 3$ -month uncontrolled passage of feces) in women. Treatment with the Leva System is by prescription and is not for everyone. Please talk to your prescriber to see if Leva System is right for you. Your prescriber should discuss all potential benefits and risks with you. Do not use Leva System while pregnant, or if you think you may be pregnant, unless authorized by your doctor. For a complete summary of the risks and instructions for the Leva System, see its Instructions for Use available at **[www.levatherapy.com](http://www.levatherapy.com)**.

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Source: Axena Health, Inc.