Interactive Pelvic Floor Muscle Training for Female Urinary Incontinence

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Preliminary Data from NESCA-REN-001: Assessment of the leva Incontinence System for treating mild-to-moderate female urinary incontinence.

PRÉCIS
The leva® Pelvic Digital Health System is an innovative intravaginal accelerometer-based system that guides pelvic floor muscle training programs to improve incontinence symptoms and condition-specific quality-of-life in women with mild-to-moderate stress and mixed urinary incontinence (UI) beginning in the first week of use during a 6-week study.

SUMMARY
The leva Pelvic Digital Health System (Renovia Inc) is an innovative movement-based interactive and integrated digital health system. It combines a pelvic floor training device incorporating intravaginal accelerometers with a smartphone application to provide sensor-collected data in numeric and graphic formats. The leva device has been FDA cleared for the rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild-to-moderate urgency incontinence in women. leva is also indicated for the strengthening of the pelvic floor muscles. In a 6-week open-label study of 23 women with mild-to-moderate stress and mixed urinary incontinence, twice-daily pelvic floor muscle training assisted by the leva Pelvic Digital Health System significantly reduced or eliminated UI symptoms in 87% (20/23) of women (p=0.001), based on the Urogenital Distress Inventory - 6 (UDI-6). Condition-specific quality-of-life, as measured by participants’ scores on the validated standardized Incontinence Impact Questionnaire – 7 (or IIQ-7)1-6, improved in all women, with a mean IIQ-7 score change from 17.6±21.6 at baseline to 0.3±1.3 (p=.0009) at the end of the study. Most women (74%, 17/23) reported no leakage during the last week of the study. Pelvic floor muscle function improved based on multiple measures, including an increase in the maximum duration of contraction (13s±12 to 187s±46, p=.0001), an increase in the maximum number of contractions in 15 seconds (5.9/s±2.0 to 9.6/s±2.4, p=.0001), and an increased maximum angle of contraction (65.1°±9.4 to 81.8°±8.7, p=.0001). The leva Pelvic Digital Health System is associated with significant improvement of UI symptoms and pelvic floor muscle performance in women with UI that becomes evident within weeks of beginning training.

FEMALE URINARY INCONTINENCE
Female Urinary Incontinence has a prevalence as high as 61% in women under 60 years of age, and the severity of urinary incontinence increases as the population ages.7 This proportion is influenced by childbirth, obesity, and in women who smoke or participate in some forms of exercise.8-13 The three primary categories of UI are stress, urgency and mixed UI. Stress incontinence, or activity-related leakage, is the most common type of UI and is defined as the complaint of involuntary leakage of urine on effort or physical exertion (e.g. sporting activities), or on sneezing or coughing. Urgency incontinence is the complaint of involuntary loss of urine associated with a sense of urgency. Mixed incontinence is when a woman experiences complaints of both stress and urgency UI. Female UI has considerable negative impact on health status, daily activity, social interaction, and condition-specific quality-of-life14 and consumes substantial healthcare and community resources.15,16

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Pelvic Floor Muscle Training (PFMT) is recognized by healthcare societies worldwide as the primary treatment for women with stress and mixed UI.\textsuperscript{19-22} PFMT (commonly referred to as Kegels\textsuperscript{30}) has been shown to reduce UI symptoms and are believed to do this by increasing levator ani muscle tone, coordination, and contraction strength, thereby providing support for the bladder neck and urethra.\textsuperscript{24} The proper performance of pelvic floor training is a combined lifting and squeezing motion of the entire pelvic floor, with the largest contribution coming from the levator ani. High-quality evidence validates PFMT as an effective, safe, and non-invasive method for managing UI symptoms.\textsuperscript{25-27} A Cochrane meta-analysis of four randomized controlled trials demonstrated a 56% cure rate in women with stress UI after performing PFMT versus only 6% in controls (relative risk 8.4, 95%CI 3.7–19.1), and PFMT participants were 17-times more likely to report cure or improvement (95%CI 4.3–69.6).\textsuperscript{25} Pelvic floor muscle training is also beneficial in treating mixed UI\textsuperscript{28} and UI-related sexual dysfunction, anal incontinence, pelvic organ prolapse, and chronic pelvic and abdominal pain.\textsuperscript{29}

Pelvic Floor Muscle Training (PFMT) is recognized by healthcare societies worldwide as the primary treatment for women with stress and mixed UI.\textsuperscript{19-22}

Despite the effectiveness of PFMT in the literature, approximately one-third of women presenting for evaluation of a pelvic floor disorder cannot properly perform voluntary squeeze-and-lift PFMT.\textsuperscript{20} Interactive systems have been used as an adjunctive approach to enhance PFMT effectiveness by providing real-time assessment of whether PFMT is being performed correctly.\textsuperscript{31,32} Measurements of muscle activity are conveyed to the patient using visual, acoustic, or tactile means. Feedback data are also useful in tracking and guiding PFMT progress over time, and may help maintain patient motivation by enhancing self-efficacy, which is an independent driver of adherence.\textsuperscript{31,33,34} Digital technology is increasingly being used to self-monitor and guide health-promoting activities, including pelvic floor training programs.\textsuperscript{35-37} Current interactive systems for PFMT extrapolate information about pelvic floor muscle activity using changes in electrical activity (sEMG or surface electromyography) or changes in vaginal squeeze pressure attributed to activation of the pelvic floor muscles.\textsuperscript{20} An important limitation of these systems is they detect only the electrical activity surrounding the device or the total overall pressure, and cannot determine specific muscle movement during training. This limitation may have consequences in that it cannot distinguish between a downward push or over-reliance on accessory muscles and a properly performed squeeze-and-lift maneuver of the pelvic floor.

The leva Pelvic Digital Health System (leva) is an innovative movement-based intravaginal pelvic floor interactive and integrated digital health system.\textsuperscript{*} It precisely detects and accurately displays real-time and historical PFMT information (Fig. 1). The system contains three primary components, i) an intravaginal detection sensor with attached cord, ii) a transmission unit that processes and wirelessly transmits the sensor-collected data to a paired smartphone, which contains iii) a custom software application, your leva, that presents the data on the screen in numerical and graphic formats. Key features of the leva system are shown in Table 1. The leva device uses six accelerometers arranged in series on an intravaginal sensor to precisely assess the movement of different sections of the sensor relative to the earth during a pelvic floor muscle contraction. This differentiates the device from other forms of pelvic floor muscle assessment, as it is a movement-based device, showing lift (or descent) of the pelvic floor in contrast to pressure or electrical activity. A properly performed pelvic floor muscle contraction results in lifting the pelvic floor, as identified by changes in the relative position of the sensors within the vagina. Thus, an increasingly strong pelvic floor lift contraction proportionately increases the angle of the intravaginal axis. This angle change is visually displayed to the leva user on their smartphone, providing feedback about proper PFMT.

\*The leva Pelvic Digital Health System is available by prescription only and should only be used as indicated by your physician. Patients should review the leva device’s Instructions for Use (available at https://renovainc.com/) for important safety information prior to use.
A) The leva consists of an intravaginal sensor and a battery-powered Bluetooth® transmitter that sends visual output of the pelvic floor angle to the patient’s smartphone.

B) The leva provides real-time PFMT coaching to the patient using either a numerical or a graphic assessment of the pelvic floor angle achieved and duration of each contraction, and,

C) stores these data in a training history file that is accessible by the patient, and with permission, their pelvic floor physical therapist, and physician.

D) The leva app provides a video representation of the pelvic anatomy during properly and improperly performed pelvic-floor muscle contractions to help the patient visualize and reinforce proper pelvic muscle action movement during training.

Table 1. Design characteristics of the leva Pelvic Digital Health System

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor External Material</td>
<td>Medical-grade silicone</td>
<td>Pliable, biocompatible, hypo-allergenic</td>
</tr>
<tr>
<td>Dimensions (intravaginal</td>
<td>110-mm long × 16-mm diameter</td>
<td>Tampon-like dimensions and shape</td>
</tr>
<tr>
<td>sensor)</td>
<td>Dimensions (power box)</td>
<td>Contains electronics, Bluetooth interface, power switch, batteries</td>
</tr>
<tr>
<td>Accelerometers in sensor</td>
<td>6 units, each with 3-axis (x,y,z) detection capability</td>
<td>High sensitivity; allows calculation of muscle contraction directionality and pelvic floor angle.</td>
</tr>
<tr>
<td>Battery type/life</td>
<td>2 × 1.5V AA batteries</td>
<td>Common type; lifespan &gt;2 months under normal use (two daily 2.5-minute training sessions)</td>
</tr>
<tr>
<td>Website interface</td>
<td>Automatic data upload to secure website</td>
<td>Chronological training results are available online to patient and physician/pelvic floor physical therapist</td>
</tr>
</tbody>
</table>

leva PELVIC DIGITAL HEALTH SYSTEM - CLINICAL EVIDENCE:

The leva Pelvic Digital Health System was recently evaluated in a 6-week open-label study involving 23 women with mild-to-moderate stress or mixed UI. The objective of the study was to assess the effectiveness of the leva in the treatment of stress and mixed UI. The mean age of study subjects was 42.0±10.7 years, with 74% (17/23) self-identifying as Caucasian. The mean BMI was 26.01±4.01 and the initial mean Urogenital Distress Inventory - 6 (UDI-6) score was 27.5±16.9.
Efficacy in UI Symptom Improvement: Significant relief of UI symptoms and improved condition-specific quality-of-life was achieved in women who performed two × 2.5-minute PFMT sessions per day with the leva (including five weekly in-person supervised training sessions each week for six weeks). Adherence to the twice daily regimen was 95% for 30 clinic sessions over a 6-week period, and 80% for 54 at-home sessions over six weeks, as reported via the leva phone app. Overall adherence was 86% for all sessions. Scores on the UDI-6, Patient Global Impression of Severity (PGI-S), and the Incontinence Impact Questionnaire-7 (IIQ-7) all demonstrated improvement. These findings began within one week of training and continued through six weeks (Fig. 2). At baseline, 13 women reported stress incontinence and 10 women had mixed incontinence. At six weeks, 20 of 23 women (87%) reported no symptoms of stress incontinence based upon the UDI-6, and 0 of 23 women (0%) reported urgency or mixed incontinence. The mean number of daily urine leaks recorded in voiding diaries decreased significantly from 2.7±2.6 incidents/day at baseline to 0.6±1.3 incidents/day at week six (78%).

The leva was recently evaluated in a 6-week open-label study involving 23 women with mild-to-moderate stress or mixed UI. (p<.001). Most women (17/23, 74%) reported no urine-leak events during the final study week. Based on the IIQ-7, condition-specific quality-of-life significantly improved in parallel to UI symptom resolution (p=.0009). Significant improvement was observed as early as week one of the study.

Using both Clinician and Patient Global Impression-Improvement assessments, after six weeks of training more than 90% of cases were deemed by both clinicians and patients to be either “very much” or “much” improved versus baseline (Table 2). All women reported improvement while none rated their health status as unchanged or worsening.

Table 2. Global improvement after 6 weeks of daily leva-assisted PFMT

<table>
<thead>
<tr>
<th>Status, n (%)</th>
<th>CGI-I 3 weeks</th>
<th>PGI-I 3 weeks</th>
<th>CGI-I 6 weeks</th>
<th>PGI-I 6 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Much Better</td>
<td>2 (9%)</td>
<td>1 (4%)</td>
<td>17 (74%)</td>
<td>17 (74%)</td>
</tr>
<tr>
<td>Much Better</td>
<td>14 (61%)</td>
<td>15 (65%)</td>
<td>5 (22%)</td>
<td>4 (17%)</td>
</tr>
<tr>
<td>A Little Better</td>
<td>6 (26%)</td>
<td>5 (22%)</td>
<td>1 (4%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>No Change</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Worse, any degree</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

CGI-I, Clinician Global Impression-Improvement; PGI-I, Patient Global Impression-Improvement
Impact on Pelvic Floor Muscles: Pelvic floor muscle performance improved significantly in women who completed twice-daily PFMT sessions with the leva based on several quantitative measures. Early and sustained improvements in the number of PFM repeated contractions over 15 seconds, contraction endurance, and pelvic floor angle-of-lift were identified during the 6-week study. These effects appeared within one week of training and continued to improve through six weeks (Fig. 3).

These effects appeared within one week of training and continued to improve through six weeks.

Figure 3. Objective measures of PFM performance after leva-assisted PFMT.

A) The maximum number of contractions that could be performed within 15 seconds increased from 5.9±2.0 (range 3-10) at baseline to 9.6±2.4 (range 5-14) at 6 weeks (p<.0001).

B) The mean maximum duration of pelvic floor muscle contraction significantly increased from 13±12 seconds (range 4-65) at baseline to 187±46 (range 60-242) seconds at 6 weeks (p<.0001).

C) The maximum pelvic floor angle with contraction increased from 65.1±9.4° at baseline to 81.1±8.7° at 6 weeks (p<.0001). Shown are means with 95% confidence intervals; p-values by repeated measures ANOVA.

Safety: Three of 23 subjects reported mild adverse events, including an upper respiratory infection (1), symptoms of UTI (1, negative urine culture) and a migraine headache (1). All resolved without sequelae.

User-Friendliness: The leva was consistently ranked as easy to use by study participants (Fig. 4). Because patient adherence to at-home treatments is dependent upon the user-friendliness of a particular therapy,6 it is critical self-guided PFMT regimens are convenient and uncomplicated to perform.

Conclusion: The leva Pelvic Digital Health System is an innovative approach to pelvic floor muscle training and digital health for women with mild-to-moderate stress or mixed urinary incontinence that markedly improves incontinence symptoms, beginning in the first week of use in this study. Patient-reported UI symptom severity, condition-specific quality-of-life and objective measures of pelvic floor muscle performance improved significantly over a 6-week study.
