ELITONE® URGE for treatment of UUI

First clinical evaluation of the ELITONE® URGE device for the treatment of female urge urinary incontinence

Gloria R Kolb, MS[1], Eric D Kolb, MS[1], Farrell Brown, BS[1], Grace Biggs, MD[2]

1. Elidah, Inc., Monroe, CT, 2. Griffin Hospital, Derby, CT

Background

Treatment options for women suffering with urge urinary incontinence (UUI) range from implantable neuromodulators to anticholinergic medications to intravaginal electrical muscle stimulators.

Perineal-applied electrical muscle stimulation provides an effective treatment for stress urinary incontinence. This external application is advantageous for its lower risk of UTI, comfort, and preference by women averse to vaginally inserted treatments. The use of this technology as a treatment for urge urinary incontinence has not been widely studied.

This prospective clinical study aims to evaluate the efficacy of perineal-applied electrical stimulation as a treatment for female UUI. Demonstrated clinical efficacy will expand the indications for use of this well-tolerated treatment modality.

Materials and Methods

Study participants were recruited through social media ads that linked candidates to a webpage detailing the study requirements. Interested candidates completed an eligibility screening questionnaire, and qualified candidates were contacted to confirm eligibility and sign informed consent documents. Eligible women were 18-80 years old with mild-moderate urge-predominant urinary incontinence. Subjects maintained a 7-day baseline log that tracked patient-centric measures including incontinence episodes, bathroom visits, and pad use. Subjects also completed the validated Incontinence Quality of Life (I-QoL) questionnaire. Exclusion criteria included current or recent pregnancy, recent pelvic surgery, BMI >35, active urinary tract infection, an implanted cardiac device or cardiac condition, more than 5 self-reported accidents per day, and predominant stress urinary incontinence.

Enrollment
(online recruitment, inclusion/exclusion, consent)

Baseline
(7-day log, verification of continued eligibility, group assignment, device delivery)

Treatment
(20 min/day, 4-5x/week for 6 weeks, daily treatment and symptom log, adverse event reporting, follow-up with study personnel)

Post-Treatment
(post-study questionnaires, device return, data review and analysis)

The investigational ELITONE® URGE device comprises a flexible electrode contoured to fit and loosely adhere to the perineal anatomy. Its four conductive regions are positioned to target the neuromuscular tissues of the pelvic floor. The electrode connects to a battery-powered control unit that outputs a modulated stimulation waveform. The user sets the intensity of the output, puts her clothes on over the device, and can move freely throughout the treatment. The ELITONE URGE device is identical to the commercially available ELITONE device except for the design of the stimulation waveform.

Two device configurations were evaluated. Configuration 1 continuously cycled through 4 seconds of stimulation at 50Hz, 4 seconds at 10 Hz, and 6 seconds of rest (i.e., no output). Configuration 2 cycled through 6 seconds of stimulation at 10 Hz, followed by 6 seconds of rest. Subjects were randomized to treatment group and study administrators were blinded to device assignment. Subjects self-administered the 20-minute treatment 1x per day, 4-5x per week for 6 weeks. Throughout the study, subjects maintained a daily log that tracked similar data to the baseline log. At the end of the study, subjects repeated the I-QoL questionnaire.

About Elidah

Elidah, Inc. is a woman-owned medical device company based in Connecticut, USA. It holds several patents for perineal-applied electrical muscle stimulation, and has been largely funded by the National Science Foundation, NIH, and the DOD. Elidah maintains ISO 13485:2016 certification and an FDA listing as a medical device manufacturer. Elidah uses WCG-IRB for review of its clinical study protocols.

The original ELITONE® device is FDA-cleared for the treatment of stress urinary incontinence. It is available over-the-counter to patients without a prescription. ELITONE is also approved by Medicare and some private insurers. Coverage typically requires a prescription, documented 4 weeks of failed pelvic floor muscle exercises, and chart notes.

ELITONE URGE was recently FDA-cleared for the treatment of urge urinary incontinence. Clinical availability of ELITONE URGE is expected mid-2023.

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Elidah

>>> 30-Second Overview <<<

Innovation: Perineal-applied electrical muscle stimulation for female urge urinary incontinence (UUI)

Study Design: 32 women with predominant UUI self-administered treatment for 6 weeks. Two device configurations (50Hz+10Hz, 10Hz). Post-treatment outcome measures compared to pre-treatment baseline, including UUI episodes, pad use, and I-QoL score.

Results:

- Urge incontinence episodes reduced by 70% (≥50% is clinically significant)
- 94% of subjects achieved some reduction in UUI episodes
- I-QoL changed by 10x clinically significant threshold
- Pad use decreased by 34%

Treatment Benefit: Convenient, non-invasive alternative to intravaginal therapies.

Results

32 subjects completed the 6-week treatment and returned all study materials. Subjects averaged 52±13 years old, a BMI of 26.1±5.2, and had been continence for 9.1±7.2 years. All subjects had previously tried Kegel exercises to resolve their incontinence, and approximately half had some familiarity with electrical muscle stimulation devices.

UUI episodes (defined as leaks plus “near misses”) reduced by 70±31%. 85% of subjects achieved a reduction of ≥50%, the threshold that FDA considers clinically significant. A similar reduction was achieved when considering only UUI leaks. Favorable changes were seen for all 22 questions of the I-QoL tool, with total score improving by 26.7±16.5 points. This is more than 10x greater than the 2.5 point change that FDA considers clinically significant. Pad use was reduced by 34±47%.

No statistical difference ($p<0.05$) was measured between Configuration 1 and Configuration 2 for any of the outcome measures. Per protocol, this outcome allowed pooling of data from the two groups.

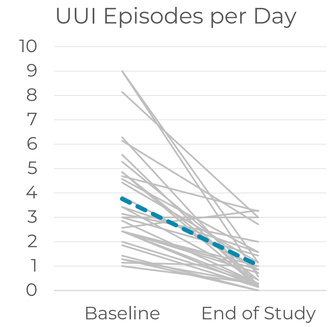
Post-hoc analysis did not reveal any notable correlations between outcome measures and demographic considerations including age, BMI, and years with incontinence.

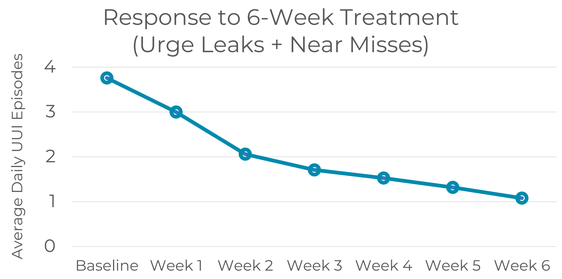
Surveys that assessed satisfaction and product usability generated favorable responses. 59% of participants reported to have improved “a lot”, and only 3% of participants (1 of 32) reported to have improved “not at all”.

No adverse events were reported.

Outcome Measure	Baseline	Last 7 Days	p-value
UUI Episodes per Day	3.8 ± 2.2	1.0 ± 1.0	<0.0001
I-QoL Score	77.2 ± 16.2	50.4 ± 16.4	<0.0001
Pads per Day	2.0 ± 1.1	1.1 ± 0.8	<0.0001
Daytime Bathroom Visits	6.5 ± 2.2	6.3 ± 2.6	0.586
Nighttime Bathroom Visits	1.5 ± 1.2	1.2 ± 1.2	0.045
SUI Leaks	1.0 ± 1.3	0.3 ± 0.5	0.005

ABOVE: *Significant changes were observed across multiple outcome measures.* ***RIGHT:*** *31 of 32 subjects achieved reduction in UUI episodes per day. Mean change shown as dashed line.* ***BELOW:*** *UUI episodes reduced steadily over the 6 weeks of treatment.*





Conclusions

The home-use study design, with no in-clinic training or direct clinician oversight, provided a pragmatic assessment of the real world use case for an over-the-counter treatment. Patient-centric incontinence outcome measures demonstrated treatment efficacy, and support the use of ELITONE URGE as a low-risk, at-home treatment for women with mild-moderate UUI. The treatment provides an alternative to more invasive and intrusive therapies, including surgery, implanted neuromodulation, intravaginal stimulation, and medications. It was well-tolerated by subjects

For patients, treating with ELITONE URGE doesn’t require a dedicated time or private place, making it convenient for busy women who might otherwise opt out of in-clinic or more intrusive alternatives. For clinicians, it provides a conservative tool to try prior to more invasive, higher risk therapies. Further, it can be implemented within a practice with negligible training or capital expense.

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