Research Report

Surface-Applied Electrical Muscle Stimulation for Self-administered Treatment of Female Stress Urinary Incontinence

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ABSTRACT

Background: Female stress urinary incontinence is effectively treated with pelvic floor physical therapy. However, many of the devices available to therapists necessitate vaginal insertion, which many women perceive as invasive. The Elitone device delivers a noninvasive alternative for delivering electrical muscle stimulation to the pelvic floor, which may promote broader access to this therapeutic modality. Further, the device's configuration enables home use, which may be used to complement in-clinic therapy sessions.
Objective: This research investigates the safety and efficacy of surface-applied electrical muscle stimulation in the treatment of female stress urinary incontinence in an at-home, patient-administered use case.
Study Design: Cohort study without control group.
Methods: Twenty female participants with mild/moderate stress urinary incontinence self-administered daily treatments with the Elitone device for 6 weeks. Participants recorded incontinence episodes and absorbent pad use in a daily log. Pre- and poststudy questionnaires were used to assess quality of life, participant satisfaction, and product usability.
Results: Incontinence episode frequency, pad usage, and quality-of-life measures improved to a clinically significant degree for 75%, 85%, and 67% of participants, respectively. The pre- to poststudy changes were statistically significant ($P < .001$) for all 3 measures. Eighty-three percent of participants were satisfied with the treatment.
Conclusion: Participants receiving treatment with the conservative, noninvasive Elitone device achieved meaningful improvement in incontinence symptoms across multiple, patient-centric outcome measures. The degree of improvement aligned with historical performance of more invasive, intravaginal therapies. The therapy may particularly benefit those women who oppose use of vaginally inserted devices. Further, although this study evaluated efficacy as a stand-alone, at-home treatment, physical therapists may realize additional benefits by using the device as an at-home complement to in-office therapy sessions.
Key Words: incontinence, muscle stimulation, noninvasive, pelvic floor

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Authors Gloria Kolb and Eric Kolb have principal ownership in Elidah, the manufacturer of the device under investigation. Author Hanson provides consulting services for Elidah.

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INTRODUCTION

Urinary incontinence is a widely prevalent condition, affecting approximately 1 in 3 women.[1–3] It is a highly stigmatized health issue that imparts significant physical, emotional, social, and financial impact. Among the several types of urinary incontinence, stress urinary incontinence (SUI) is the most prevalent among women, with 82% of women with incontinence presenting with SUI symptoms.[4] Nonsurgical treatment for SUI typically comprises retraining and strengthening the pelvic floor muscles through active muscle contraction (ie, Kegel exercises, biofeedback) and/or intravaginal electrical muscle stimulation (EMS). Clinic-based treatment sessions allow pelvic floor physical therapists the opportunity to directly assess the condition, administer treatment, provide instruction, and monitor improvement. These sessions typically occur 1 to 3 times per week, a frequency that is in part driven by the availability of

patients to visit the clinic and by financial reimbursement policy. There are potential benefits to prescribing at-home therapies,[5] but this practice has notable limitations. Pelvic floor exercises (eg, Kegels) can be difficult to perform correctly (1 in 4 fails to achieve a contraction) and with adequate frequency and/or contraction duration.[6] Similarly, some intravaginal EMS devices are indicated for home use, but their invasive nature necessitates use in a private place and for a dedicated time, making it an inconvenient solution for women with busy lifestyles. Further, women can have emotional, physical, or cultural aversions to use of vaginally placed devices, which diminishes the utility of intravaginal EMS as an at-home treatment option.[7,8] Accordingly, the need exists for an improved home-use device that is convenient, noninvasive, and easy to use for women treating SUI.

Electrical muscle stimulation has been used for decades as a conservative treatment for SUI. The therapy delivers milliamps of current to the pelvic floor muscles and surrounding structures (eg, pudendal nerve) with the intent of inducing a therapeutic muscle contraction. When administered over multiple weeks according to a prescribed regimen, incontinence symptoms are reduced or eliminated. In treating SUI, electrodes are traditionally positioned intravaginally, as this placement is thought to directly target the muscles and structures that affect continence. However, Correia et al[9] showed that a pattern of surface-applied (ie, cutaneous) electrodes placed in the perineal region was as effective as intravaginal electrodes at retraining the pelvic floor muscles. Other researchers have published similar results describing clinically significant reductions in SUI symptoms with perineal-applied EMS.[7,8,10–14] These studies utilized EMS parameters and treatment regimens that were not dissimilar from intravaginal EMS treatments, or from more general musculoskeletal use of EMS; stimulation waveforms ranged from 1 to 100 Hz, amplitudes were user-adjusted, sessions were administered 2 to 4 times per week, and occurred over 3 to 8 weeks. The authors cited advantages of perineal-applied EMS including its utility with women averse to intravaginal therapies and a reduced risk of vaginal infection. However, a limitation was that the referenced devices did not enable reliable self-application of the perineal electrodes. Rather, those studies required a clinician to position and monitor multiple electrodes throughout the treatment while the patient reclined on an examination table. Although a tenable research protocol, that implementation is not a practical solution for routine clinical practice.

These advantages and limitations suggest the opportunity to provide perineal-applied EMS in a form factor suitable for self-application and home use. The newly developed Elitone device (Elidah, Monroe, Connecticut) uniquely satisfies this need. It comprises a small EMS controller and a disposable, one-size-fits all perineal-applied electrode that enables noninvasive, discrete, hands-free, at-home treatment (Figure 1). By eliminating the intravaginal probe of traditional incontinence EMS devices, women may be more willing to initiate and complete a full course of treatment. Further, the Elitone device, which was recently cleared for prescription and over-the-counter use, may particularly benefit women with limited access to pelvic floor physical therapy services, either due to distance (ie, rural communities) or health insurance. Whether under the supervision of a health care provider or with independent home use, the device promises to enable higher adoption and compliance among women with stress incontinence.

Favorable results from acute, single-session treatments with Elitone were previously reported.[15] That work demonstrated that women could successfully self-apply the electrode, and it identified stimulation parameters that achieved comfortable contraction of the pelvic floor muscles. The purpose of the present study is to investigate the efficacy of the Elitone device as a conservative, self-administered treatment for female SUI over 6 weeks of home use.

METHODS

Participants

Participants were recruited from the senior author's practice and through social media ads that linked candidates to a webpage detailing the study requirements. Interested candidates completed an online eligibility screening questionnaire that queried the study inclusion/exclusion criteria, and qualified candidates were interviewed by phone to verify eligibility and to sign informed consent documents. Eligible women were 18 to 80 years old with predominant SUI as defined by responses to standard questions

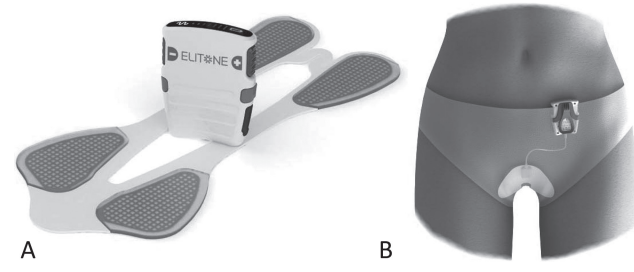

Figure 1. (A) The Elitone device comprises a disposable electrode with 4 conductive regions and a control unit that enables the user to increment and decrement treatment intensity level. (B) The electrode is placed directly against the perineal tissues. The patient wears her clothes over the device and can resume other activities while receiving treatment.

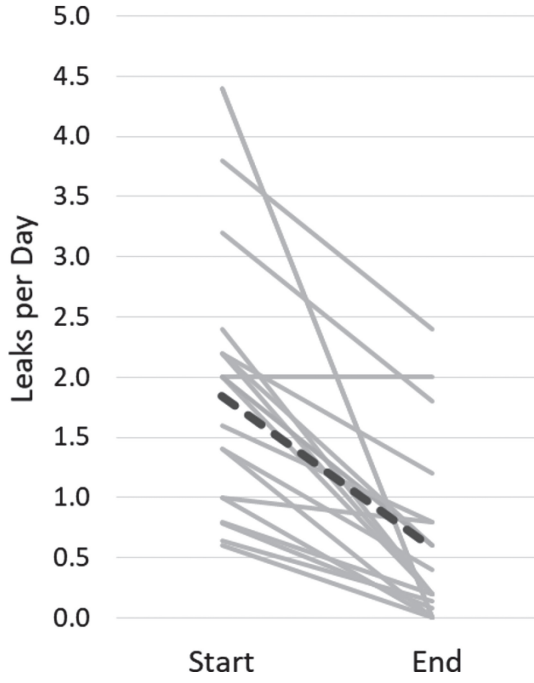

Figure 2. Incontinence episodes per day decreased for 19 of 20 participants in the study. Fifteen participants achieved a reduction of 50% or more. Average change is depicted as a dashed line.

from King's Health Questionnaire ("Do you lose urine with physical activities such as coughing, sneezing running?" "Is it very difficult to control when you have a strong urge to urinate?" and "Are more of your incontinence episodes due to a strong urge to urinate rather than from abdominal pressure such as sneezing?"), a validated and widely used instrument designed to allow women to self-assess the type and severity of their incontinence.[16–18] Inclusion criteria for symptom severity were a self-reported minimum of 2 urinary incontinence episodes per 36 hours and no more than 5 urinary incontinence episodes per 24 hours (ie, mild-moderate symptoms). Exclusion criteria included current or recent pregnancy, recent pelvic surgery, body mass index (BMI) more than 30, active urinary tract infection, an implanted cardiac device or cardiac condition, and predominant urge urinary incontinence (UUI) (ie, an affirmative response to the third question of the King's Health Questionnaire) among others.

Recruitment targeted 20 participants fulfilling the study requirements. Given the use of social media to recruit participants, which results in a participant population without any preexisting relationship with the researchers, it was expected that the number of participants lost to follow-up would be relatively high and recruitment efforts were scaled accordingly. Western IRB approved the study protocol (#W15245425.0).

Device

The Elitone device delivers EMS through the perineal region to stimulate the pelvic floor muscles and surrounding structures. It is composed of 2 components, a disposable electrode and a reusable control unit. The thin (<2 mm) electrode has an hourglass shape and fits the perineal region, with the anterior end positioned proximate the pubic symphysis and the posterior end positioned near the ischial tuberosities. Four electrically conductive regions positioned at the extents of the electrode use hydrogel to comfortably adhere the device to the skin and efficiently transmit electrical stimulation to the adjacent tissues. The electrode's shape and provided instructions enable women to self-apply the one-size-fits-all electrode in the correct anatomic placement without prior experience with EMS devices.

Electrical stimulation is generated by a wearable, battery-powered control unit connected to the electrode via a short cable. The control unit provides an interface that allows the patient to initiate treatment and set the stimulation intensity at a desirable level. The device outputs 50-Hz and 10-Hz stimulation frequencies, modulated with a 2000-Hz carrier waveform. The 50-Hz portion of the treatment is intended to contract the pelvic floor for treating SUI symptoms and the 10-Hz portion is intended to relax the detrusor muscle for treating UUI.[19] Although the device delivers stimulation aimed at treating both SUI and UUI symptoms (similar to some available intravaginal devices), the present investigation is solely focused on SUI efficacy outcomes. Modulation is used as a technique for minimizing discomfort at the electrode-tissue interface during treatment sessions.[20] The device delivers a defined treatment regimen comprising 4 seconds of stimulation at 50 Hz, 2 seconds of stimulation at 10 Hz, and 6 seconds of relaxation (ie, no output), after which the cycle is repeated for a total of 20 minutes. Throughout treatment the user has the ability to increment or decrement the stimulation intensity, and after 20 minutes the device turns off automatically.

Procedure

After providing informed consent, participants were mailed the Elitone device, a description of the patient protocol, pre- and posttreatment questionnaires, and a daily log. Questionnaires included questions pertaining to medical history, the validated Incontinence Quality of Life survey (I-QoL),[21] pad usage, treatment satisfaction queries, and feedback pertaining to the device's usability (ie, human factors testing). In the daily log, participants maintained records of incontinence episodes, treatment session completion, and treatment session intensity. Study participants also used the daily log to comment on their experiences

with the treatment, including documenting incidents that might be considered adverse events.

Product training was provided via a user manual (included in the packaging of each Elitone device) that detailed proper use through text and illustrations. Women were instructed to self-administer the preprogrammed 20-minute treatment session 4 to 5 times per week for 6 weeks. Treatment intensity was controlled by the user and according to instruction in study materials describing a strong but comfortable muscle contraction. Study personnel contacted the participants via phone or e-mail to confirm receipt of the study materials and to respond to participant questions as applicable. At the end of the study, participants were again contacted by study personnel and instructed to complete the questionnaires and return all study materials. During a final phone conversation, study personnel interviewed each participant, followed up on missing information, and made specific inquiry into possible adverse events had may have occurred during the study.

Data Analysis

Primary outcome measures were the reduction in incontinence episodes per day, a favorable change in the I-QoL score, and a reduction in pad use—all 3 of which are identified as meaningful, patient-centric outcome measures in guidance documents published by the US Food and Drug Administration.[22] Pre- and poststudy incontinence episode frequency was defined by averaging the leaks-per-day data from the first-5 and last-5 entries in the daily logs. Subjects with prestudy incontinence episode frequencies of less than 0.5 episodes per day were excluded from the analysis, as they were considered to not meet a minimum meaningful level of incontinence severity. A paired Student's *t* test was used to characterize pre- to poststudy change, with a *P* value of .05 identified as representing statistical significance. A reduction in leaks per day greater than or equal to 50% is often considered clinically significant.[22] Accordingly, participants achieving this 50% threshold were considered responders, and the calculated responder rate informed analysis in which comparisons to historical controls were made. A similar approach was used in analyzing the I-QoL scores, with a change of 2.5 points considered clinically significant.[22] As with the incontinence episode frequency measure, clinical significance for pad usage reduction was set at 50%, although only participants who reported regular pad usage in their prestudy questionnaires were included in the analysis.

RESULTS

Twenty-nine women provided informed consent, received the study materials, and presumably initiated treatment. One participant withdrew from the study after 7 treatments due to time limitations associated with a relocation. Five participants were lost to follow-up without returning study materials, so it is uncertain if or for how long they administered treatment. Three women recorded less than 0.5 leaks per day in the first week of their daily log and were excluded from subsequent analysis. This resulted in a total of 20 participants who satisfied the study requirements.

Table 1 summarizes the demographic makeup of the participants. This composition of ages, BMIs, and incontinence history is aligned with the Elitone device's intended use and product labeling, and it is broadly representative of women likely to present with mild-moderate urinary incontinence. Half of the participants had pure stress incontinence and the other half had mixed incontinence (ie, stress and urge symptoms) with predominant SUI symptoms. Sixty-five percent of the women had previously completed a regimen of Kegel exercises or other pelvic floor therapy without satisfactory results.

Treatment frequency started at 5.1 ± 1.0 treatments per week and reduced to 4.3 ± 1.3 in the sixth week, representing relatively consistent use of the device throughout the study. Treatment intensity averaged 21 ± 6.5 on the device's 0- to 35-point scale, and that value did not notably change from week to week. Assuming a 1000-Ω tissue impedance, the average intensity level corresponds to a peak-to-peak voltage of 45 V and a root mean square current of 11 mA.

Leaks per day were reduced by 71% ± 29% over the course of treatment, from 1.8 ± 1.0 to 0.6 ± 0.7 ($P < .00001$, Table 2; Figure 2). Seventy-five percent of participants had a clinically significant reduction in leakage episodes (ie, ≥50%). I-QoL scores increased (improved) by 14.6 ± 13.5 points, from 70.3 ± 17.9 to 84.8 ± 17.4 ($P < .0003$), with 85% of participants achieving a clinically significant (ie, 2.5-point) improvement in their I-QoL score. Five questions in the 22-question I-QoL questionnaire changed favorably by 1 or more points on the 5-point scale, including: "I worry about coughing or sneezing because of my incontinence," "I worry about where toilets are in new places," "I get less

Table 1. Participant Demographics

Characteristic (N = 20)	Average (SD)
Age	46.4 (12.4)
Body mass index	25.9 (3.0)
Years with incontinence	9.7 (9.9)
Leakage episodes per day[a]	1.6 (1.7)
Pads per day	1.4 (1.2)
[a]Self-reported values from prestudy questionnaires (not daily log data).	

Table 2. Study Results–Paired Sample *t*-Test Statistics for Changes in Daily Leakage, I-QoL Score, and Daily Pad Usage

Outcome Measure	n (Pairs)	First Week/Prestudy Mean (SD)	Last Week/Poststudy Mean (SD)	SE of Difference	95% CI of Difference	*t* Value	*P* Value
Leaks per day	20	1.84 (1.04)	0.58 (0.73)	0.21	0.82 to 1.70	6.02	<.0001
I-QoL score	20	70.3 (18.0)	84.8 (17.4)	3.21	−21.3 to −7.8	4.54	<.0002
Pads per day	15	1.8 (1.1)	0.8 (0.8)	0.25	0.46 to 1.54	3.94	<.001

Abbreviations: CI, confidence interval; I-QoL, Incontinence Quality of Life; SD, standard deviation; SE, standard error.

enjoyment out of life because of my incontinence," "I feel like I have no control over my bladder," and "I worry about having sex because of my incontinence." Among the women who used pads to manage their incontinence symptoms (n = 15), average daily pad use dropped 57%, from 1.8 ± 1.1 to 0.8 ± 0.8 ($P < .001$), with 67% of participants achieving a clinically significant (ie, ≥50%) improvement. Subgroup analysis comparing outcomes of women with pure SUI to those with mixed incontinence did not reveal any notable differences. Similarly, there were no strong correlations between measured changes in outcome measures and factors including BMI, age, and years of incontinence.

Surveys that assessed satisfaction and product usability generated favorable responses. Eighty-three percent of women responded that they were satisfied with the treatment. One-hundred percent of the participants reported that the electrode shape and materials made it comfortable to wear, and all participants reported that the stimulation was comfortable. Although not a requirement of the study protocol, 60% of the women shaved or trimmed hair in their pubic region to accommodate placement of the electrode. Eight-five percent of women reported that the electrode was appropriately sticky, and among the 15% who suggested changing the adhesiveness there was a mix of preferences for making the device more or less adhesive. No adverse events were reported that resulted in an injury or health risk.

DISCUSSION

Incontinence episode frequency, pad usage, and quality–of-life measures improved to a clinically significant degree for 75%, 85%, and 67% of participants, respectively. This performance is on par with more invasive (ie, vaginal) device therapies that suffer from poor patient adoption and compliance, including biofeedback, weights/cones, and intravaginal EMS.[23] Elitone is not intended to provide superior outcomes to these invasive interventions, particularly within the context of physician-controlled clinical studies in which patient compliance may be artificially elevated relative to pragmatic home use of the same devices. Rather, Elitone provides an alternative therapy with similar efficacy that can substantially benefit women who might otherwise have opted out of treatment.

Factors including comparative treatment selection, study size, participant recruitment and retention, and external validity were all considered in developing the study protocol. Although conducted as a cohort study without control, the study could alternately have utilized a control arm in which an equivalent population received either "no treatment" or treatment with a sham device. Under both control arm conditions some individuals might reasonably be expected to realize clinical improvement, but given the average time the participant population had been dealing with incontinence (almost 10 years) and the natural progression of incontinence symptoms, the expected response rates within a control group would be low. In its meta-analysis of nonsurgical treatments for female urinary incontinence, the Agency for Healthcare Research and Quality identified 28 studies across 6 pelvic floor treatment types (eg, pelvic floor muscle training, biofeedback, intravaginal EMS, percutaneous EMS, and magnetic stimulation) that included comparisons to nonactive controls. Average response rates (ie, improvement) from the nonactive control groups ranged from 14% to 22% across each of the 6 categories.[23] Accordingly, anticipating a large difference between the Elitone device's performance and the reported outcomes for nontreatment control groups, the authors designed this study as a cohort study without a control, eliminating the need to submit women to 6 weeks of daily therapy with minimal expectation of a meaningful improvement.

As a surrogate to use of a control arm, measured response rates with the Elitone device can be compared to historical performance of controls. Using the conservative 22% responder rate from referenced meta-analysis as the null hypothesis value in a 1 proportion test, one finds a statistically significant difference between the observed Elitone treatment and an expected control ($P < .001$, 95% confidence interval: 50.0-91.3). This result also supports the suitability of the 20-subject study size, which power analysis ($\alpha = 0.05$, power = 80%) shows to be capable of identifying a statistical difference in groups with a treatment response rate as low as 50%. Controlled studies by other researchers have used similar enrollments.[7,9,24,25]

The nature of the study design, in which participants used the device at home and without visits to a medical clinic, made use of additional outcome measures like pad weight tests and digital muscle assessments prohibitive. Although such measures are typically included in clinic-based incontinence studies because they provide independent objective data, study participants typically do not associate such measures with symptom severity.[22] The outcome measures used in this study were intentionally patient-centric. Another potential limitation of conducting a study without visitation to a medical clinical is the risk of participants providing incorrect information during enrollment (eg, BMI) or over the course of treatment (eg, total number of sessions). To minimize this risk, study personnel thoroughly reviewed participants' case report files for inconsistencies that would suggest such occurrences.

Clinical protocols investigating EMS for treating SUI typically last 4 to 12 weeks, making the 6-week duration of this study relatively short. An extended treatment duration would have allowed participants to continue ongoing improvement, which may have particularly benefited the women who started with more severe symptoms. Although the study was not designed to assess long-term outcomes, follow-up with several participants confirmed that improvements were maintained for as much as 1 year following treatment.

This study was conducted in a home environment, utilized minimal exclusion criteria, and was conducted without intervention by a health care professional during the 6 weeks of therapy. Although these could be considered study limitations, the study design provided a pragmatic assessment of a use scenario representative of an "over-the-counter" device. Within the context of a clinical study, engagement with a health care professional (eg, more stringent patient screening assessments, face-to-face instruction on device operation, and regular treatment compliance monitoring) is only expected to increase the measured efficacy of the therapy. Additional benefits may also arrive from the use of Elitone in conjunction with in-clinic offerings including education, pelvic floor exercises, manual therapy, and biofeedback.

CONCLUSION

Perineal-applied EMS delivered with the Elitone device provided effective treatment of SUI. Device features enabling noninvasive, self-administered treatment provide advantages over vaginally inserted therapies, particularly for women unable to access pelvic floor physical therapy and those resistant to use of invasive devices. These same features provide the opportunity to use the Elitone device as a tool to complement other clinic-based pelvic floor therapies.

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