

# Effect of surface electrical stimulation in a seated position on pelvic floor muscle functions, urinary leakage, and quality of life in women with stress urinary incontinence

**Ui-jae Hwang**

Yonsei University - Wonju Campus

**Min-seok Lee**

Sophie-Marceau Women's Clinic

**Young-shin Kim**

Shera Women's clinic

**Sung-hoon Jung**

Yonsei University - Wonju Campus

**Oh-yun Kwon** (✉ [kwonoy@yonsei.ac.kr](mailto:kwonoy@yonsei.ac.kr))

Yonsei University - Wonju Campus <https://orcid.org/0000-0002-9699-768X>

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## Research article

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## Abstract

**Background** The aim of this study was to demonstrate the effect of surface electrical stimulation in a seated position (SESSP), as pelvic floor muscle (PFM) training, on PFM functions (time to reach maximal pressure [TRMP], muscle strength, power and endurance), urinary leakage and quality of life in patients with stress urinary incontinence (SUI).

**Methods** Women with SUI were randomized into an SESSP group (n = 18) or control group (n = 18). Quality of life were assessed by the Incontinence Quality of Life Questionnaire (I-QOL). Ultra-short pad test results and PFM functions were measured by perineometer. Changes in the outcomes were assessed before and 8 weeks after SESSP training.

**Results** Thirty-three participants were included in the analysis. There were significant differences in I-QOL (avoidance and limiting behaviors, psychosocial impacts, social embarrassment and total score) in between (SESSP vs. control group) and within (pre vs. post) group analyses. Significant increases in PFM strength, power, and endurance, and significant decreases in the TRMP and pad weight, were observed between (SESSP vs. control group) and within (pre vs. post) groups.

**Conclusion** SESSP in a seated position can be recommended to improve QOL, urinary leakage, and PFM functions in SUI patients. Trial registration Current Controlled Trials KCT0003357 (the date of registration: 2018.11.16) and retrospectively registered.

## Background

Stress urinary incontinence (SUI) is the involuntary loss of urine on exertion, effort, sports activities, coughing, or sneezing, as defined by the International Continence Society (ICS) [1]. The ICS reports that half of female urinary incontinence cases are attributable to SUI [1]. More than 30% of women develop SUI within 5 years after their first vaginal delivery [2]. Although SUI impacts quality of life (QOL), leading not only to physical limitations but also to psychosocial problems, patients often underreport SUI [3]. For mild to moderate SUI, all guidelines recommend noninvasive or conservative treatment before invasive treatment, because this can lead to better outcomes [3]. Noninvasive treatments include physical and behavioral therapy, such as bladder or pelvic floor muscle training (PFMT), electrical stimulation (ES), and vaginal cones.

The goal of noninvasive treatment for SUI is to enhance pelvic floor muscle (PFM) functions by increasing speed, power, strength, and endurance [4]. PFMT is a guideline-recommended primary treatment for SUI that aims to increase urethral pressure and tone, as well as PFM functions, and to decrease urethral hypermobility [2], thus preventing loss of urine and promoting continence [2]. However, it is difficult to initiate and train selective contraction of the PFM, particularly in incontinence patients who have difficulty with contracting the PFM selectively unassisted [5]. Also, the literature has shown that inappropriate PFM contractions can exacerbate the symptoms of SUI [5].

ES for PFMT could improve QOL, urinary leakage, and the pressure of selective PFM contractions. ES for PFMT has an improvement rate of 74%, and a cure rate of 30–60%, in patients with SUI [6]. Previous studies have reported the effects of ES as a treatment for SUI performed with superficial, anal, and intravaginal electrodes [4, 7, 8]. ES via transvaginal electrodes is frequently used in clinical practice, but the use of transvaginal electrodes could potentially be limited by pain, intolerance of the high stimulation intensity, discomfort associated with the insertion of electrodes, difficulty of hygienic management, and/or bleeding [9, 10].

Recently, the EasyK7 (Alphamedic Co., Ltd., Daegu, Korea) device was designed for contracting the PFM via ES using cutaneous electrodes inserted into both perivaginal and sacral regions during sitting. Previous studies reported the effects of surface electrical stimulation in the supine or hook-lying position for treating urinary incontinence, which can be performed with placement of cutaneous electrodes in the perivaginal or sacral region [7, 11, 12]. However, to date, little has been reported on the effectiveness of ES for PFMT performed in a seated position using cutaneous electrodes implanted into both perivaginal and sacral regions for the treatment of SUI. Additionally, there has been no study showing specific improvements of PFM functions (muscle strength, power, and endurance) after applying surface electrical stimulation in a seated position (SESSP). Therefore, it is necessary to investigate the effectiveness of novel SESSP techniques for improving urinary incontinence and QOL.

The purpose of the present study was to determine the effectiveness of SESSP as PFMT performed in a seated position, as indexed by PFM functions (time to reach maximal pressure [TRMP], muscle strength, power and endurance), urinary leakage, and QOL. We

hypothesized that PFM functions and QOL would improve, and urinary leakage would decrease, after 8 weeks of SESSP as PFMT in the experimental group compared with the control group.

## Materials And Methods

### Subjects and design

This was a randomized controlled trial (RCT) with an investigator-blinded parallel randomization (1:1) design (control and SESSP groups). The present study was performed at an obstetrics and gynecology clinic in Seoul, Korea, from August 2018 to November 2018. The sample size was determined *a priori* (version 3.1.3; University of Trier, Trier, Germany) in a pilot study with three participants in each group (experimental and control groups). The sample size was calculated according to a power of 0.80, alpha level of 0.05 and effect size *f* of 0.917. The analysis indicated that more than six subjects were required. The women were recruited via advertisements included provided telephone contact information for the study. After the initial contact, visits were scheduled to review the participant suitability according to the inclusion and exclusion criteria of the study, and incontinence severity was checked via the Ingelman–Sundberg scale, as administered during an interview [13].

Inclusion criteria [14] were 1) SUI diagnosed by a urogynecologist, 2) a leakage episode occurring more than once a week, 3) generally healthy (apart from SUI), 4) body mass index < 30 kg/m<sup>2</sup>, 5) age between 30 and 60 years, 6) non-smoker, 7) not addicted to alcohol or drugs, and 8) successfully completed medical screening questionnaire. Exclusion criteria [14] were 1) urogenital prolapse grade III or higher, 2) cardiac pacemakers, 3) devices implanted in the pelvis or hip joint, 4) pregnancy/planning to get pregnant, 5) pelvic or abdominal surgery within the last 6 months, 6) cognitive impairment, 7) concomitant treatment for SUI during the trial period, 8) neurological or psychiatric disease, and 9) urinary tract infection.

A total of 36 participants who met the inclusion criteria were allocated to control and SESSP groups through a list of random numbers generated by online randomization software ([www.randomization.com](http://www.randomization.com)) (Figure 1). Before the study, all procedures were explained to the participants, who then signed informed consent forms approved by the Institutional Review Board (1041849-201806-BM-056-01).

### Surface electrical stimulation device

An SESSP device (EasyK7) with three cutaneous electrodes placed in perivaginal (two electrodes) and sacral regions (one electrode) was used to stimulate the PFM and surrounding structures. Three cutaneous electrodes were inserted into the bottom and back of the SESSP device. This allowed for stimulation, via direct contact, of both the perivaginal and sacral regions, and created an electromagnetic field that stimulated the PFM while the participant sat on the EasyK7 (Figure 2). The initial stimulation amplitude was set by the physical therapist to determine the most comfortable level for each participant. The EasyK7 delivered biphasic, asymmetric impulses of 25 Hz, and controlled the pulse (11 s) and rest (11 s) durations. The mean intensity among all participants was  $19.13 \pm 5.47$  mA (range: 2.5 to 30 mA). Each EasyK7 session was 15 minutes in duration.

### Intervention

Participants in the SESSP group were provided with an EasyK7 device, underwent their first EasyK7 session on site, and were educated on proper device usage, management, and cleaning. Individuals who experienced the SESSP sensation to be aversive were excluded from the study. Participants were instructed to use the device once a day (15-min session) 5 days a week for 8 weeks. All participants participated an EasyK7 session designed to determine the maximum stimulation amplitude that they could tolerate.

The Control group underwent walking for 10 min and restricted PFMT regarding the PFM or abdominal muscle contraction. We gave and educated the EasyK7 to control group as a reward for participating in the experiment after 8 weeks. Both groups were assessed at baseline and after 8 weeks with repeated QOL questionnaires, as well as with ultra-short perineal pad tests and measurements of PFM functions performed using a perineometer.

## Outcomes

The outcome of QOL was determined by patient self-assessment. Testers were blinded to the participant's responses to the questionnaires. The I-QOL evaluated incontinence-specific QOL [15]. The I-QOL consists of three health-related QOL factors: avoidance and limiting behaviors (eight items), psychosocial impact (nine items), and social embarrassment (five items); the Korean version was used in this study [16]. The I-QOL has 22 items, each scored using a five-point scale. Three subscale scores and a total score are calculated. Scores for the 22 items were summed and then adjusted according to a 0–100 scale, with higher scores indicating higher QOL [15].

The objective status of incontinence was indicated by the ultra-short perineal pad test results and PFM power, strength, endurance, and TRMP was measured by perineometer. The ultra-short perineal pad test [17] was performed to assess urinary leakage status, as follows. The participants were allowed to empty their bladder, and any remaining urine was removed using a catheter without anesthetic gel. Then, the bladder was filled with 300 mL sterile water by a gynecologist using a catheter. For the pad test, the participants were provided with a pre-weighed sanitary diaper to place inside their underwear. Participants were instructed to perform a standardized physical activity for 1 minute at a submaximal level: jumping with feet apart and then together, jogging in place with high knees, and jumping up and down; 20 repetitions of each exercise and additional jogging in place were performed until 1 minute had passed [17]. After 10 minutes, the total amount of urine leakage was determined by weighing the pad.

The assessments of PFM functions were performed in a hook-lying position for all participants using a vaginal pressure measurement device. The VVP-3000 perineometer (QLMED Ltd., Gyeonggi-do, Korea), which is a vaginal probe 24 mm in diameter and 115 mm in length with an active surface measurement length of 66 mm, was used. The vaginal probe is connected to a microprocessor with latex tubing, allowing for transmission of pressure readings when the inserted part is compressed by external pressure. The baseline pressure value was recorded in mmHg with no voluntary PFM contraction, and the device was then zeroed. Participants were asked to contract their PFM and squeeze with maximum effort for 2–3 seconds. They were instructed to pull their PFM in and up as much as possible, and with no use of extra-pelvic muscle contraction. The measurement was taken before the first contraction and was displayed as a flat curve, after the participants had been instructed to relax and given time to slowly breathe in and out [18]. PFM strength was given by the difference between the resting and peak pressure measurement, and reported as the mean of two maximal pressures (in mmHg) [18]. TRMP was measured from the onset of contraction until maximal pressure was reached, and recorded in seconds. Measurement of muscle power required the participants to perform the contraction at maximal pressure as fast as possible. The present study defined PFM power as PFM strength/TRMP (mmHg/s). Local muscular endurance is the ability of a muscle to sustain sub-maximal or maximal force, assessed as the time over which a person is able to maintain a maximal static or isometric contraction [18]. PFM endurance was measured as the mean contraction pressure for 10 s, during one attempt (mmHg).

## Statistical analysis

All statistical analyses were conducted using SPSS software (ver. 18.0; SPSS Inc., Chicago, IL, USA). A *p* value of 0.05 was used to indicate statistical significance. Kolmogorov–Smirnov Z-tests were used to verify that the data were normally distributed. Analysis of covariance (ANCOVA) was used to compare the groups before and after the intervention, with the baseline values used as covariates. Data are presented as mean ± standard deviation. The effect sizes and confidence interval (CI) for the primary outcomes were calculated to determine the clinical significance of the data. An effect size (*r*) is constrained between 0 (no correlation) and 1 (perfect correlation); in this study,  $0 \leq r < 0.1$  was classified as no effect,  $0.1 \leq r < 0.3$  as a small effect,  $0.3 \leq r < 0.5$  as a moderate effect, and  $r \geq 0.5$  as a large effect.

## Results

Thirty-six participants were randomly divided between the SESSP and control groups (n = 18 participants per group). However, two participants in the SESSP group and one in the control group dropped out, citing a lack of time. Therefore, 33 participants completed the interventions and were included in the analysis (Table 1 and Figure 1).

Table 2 shows the outcomes, respectively, before and after the intervention (Table 2). There were significant differences in the I-QOL avoidance and limiting behaviors parameter between the groups (mean change: -12.798, 95% CI: -17.887 to -7.709, effect size: 0.468,  $p < 0.001$ ), and in psychosocial impacts (mean change: -13.463, 95% CI: -19.734 to -7.193, effect size: 0.391,  $p < 0.001$ ), social embarrassment (mean change: -15.129, 95% CI: -22.964 to -7.294, effect size: 0.341,  $p < 0.001$ ) and total score (mean change: -10.990, 95% CI: -15.759 to -6.220, effect size: 0.425,  $p < 0.001$ ).

A significant difference was observed between groups in pad weight (mean change: 4.466, 95% CI: 2.298 to 6.634, effect size: 0.371,  $p < 0.001$ ). Regarding the PFM functions, there were significant differences between groups in TRMP (mean change: 0.190, 95% CI: 0.022 to 0.357, effect size: 0.151,  $p = 0.028$ ), strength (mean change: -2.973, 95% CI: -5.605 to -0.341, effect size: 0.151,  $p = 0.028$ ), power (mean change: -8.583, 95% CI: -13.111 to -4.055, effect size: 0.333,  $p = 0.001$ ), and endurance (mean change: -3.508, 95% CI: -6.006 to -1.009, effect size: 0.215,  $p = 0.008$ ).

## Discussion

Previous studies have demonstrated the benefits of PFMT for SUI [7]. Conventional ES devices for PFMT generally use a vaginal or anal electrode, which is invasive and often causes discomfort and injury and leads to low compliance. This can largely be attributed to the fact that the size of the vaginal space limits electrode size and the ability of the user to reach an intensity sufficient to elicit PFMT, given the relatively high current density [14]. Thus, the evidence supporting the use of PFMT employing ES for SUI has been equivocal [10, 14]. After 8 weeks of SESSP for PFMT, the present study observed improvement in PFM functions, urinary leakage and QOL. SESSP for PFMT over 8 weeks was effective for treating SUI, demonstrating that this is a good option for improving PFM functions, urinary leakage and QOL.

Regarding PFM strength measured by perineometer to assess PFM contraction pressure, a previous study also found an increase in pressure following SESSP [7]. The present study evaluated various PFM functions based on perineometer data. Muscle strength was defined by Sale as the peak force during a maximal voluntary contraction, while muscle power was defined as the rate at which mechanical work is performed under a given set of conditions [19]. Muscle endurance is the ability of a muscle to sustain near maximal or maximal force, and is given by the time over which a person is able to maintain a maximal static or isometric contraction [18]. After 8 weeks of SESSP training in the present study, TRMP was significantly decreased, and PFM strength, power, and endurance were significantly increased. Also, there were significant differences in PFM functions between factors (SESSP group vs. control group).

The increases in PFM functions after SESSP training can be explained as follows. First, it may have been due to stimulation of the pudendal nerve by SESSP [20, 21]. Because surface electrode in sacral region could stimulate pudendal nerve, thus strengthening its muscle fibers, improving electric activation, and increasing proprioception and coordination during pelvic floor contraction [21]. Second, electrode pad in sacral region could restrict pelvic posterior tilt with sacral nutation movement. Sacral counter-nutation movement could more contract PFM compared to sacral nutation movement [22]. Thus, restriction of pelvic posterior tilting might more contract PFM during SESSP. Third, PFM contraction on ES could cause perturbations in myofibers and the extracellular matrix in the case of stimulus overload of the PFM [23]. In addition, the order of motor unit recruitment (from smallest to largest, according to Henneman's size principle) is controversial in ES-evoked muscle contractions; a more reasonable explanation is the random pattern of recruitment of fast- and slow-twitch muscles [23]. PFM is composed of 70% type I slow-twitch fibers and 30% type II fast-twitch fibers. Thus, ES-evoked contractions could stimulate the PFM according to the random pattern of recruitment of fast- and slow-twitch muscles, and enhance PFM strength and power by increasing the recruitment of fast-twitch muscles, and endurance by increasing the recruitment of slow-twitch muscle. Also, a previous study reported that significantly decreased force occurred after 30 seconds of high-frequency (75 Hz) EMS [24]. During this period of high-frequency force fatigue, increased force occurred at a low frequency (20 Hz) [24].

Previous studies have found improvements in urinary leakage, as evaluated by 1-h pad tests in women treated with SESSP, which is consistent with the results of the present study [7, 8]. Another study reported similar improvements in 20-min pad tests [4]. In the present study, pad weight decreased significantly after 8 weeks of SESSP training and there was a significant difference between the SESSP and control groups.

Currently, QOL is considered to be more relevant than quantitative measurements, because it reflects the participants' satisfaction with the treatment. This study found significant improvements in avoidance and limiting behaviors, psychosocial impact, social embarrassment, and total I-QOL score, both within (pre vs. post) and between (SESSP group vs. control group) groups. Two previous studies also reported improvements in QOL after SESSP, although this was assessed using the King's Health Questionnaire [7, 8].

The decrease in urinary leakage during pad tests and increase in I-QOL after 8 weeks of SESSP training may have been due to increasing PFM functions affecting the proprioception and coordination of pelvic floor contractions during situations that cause SUI [7]. During impact activities, such as running, jumping, and dancing, the PFM power requirement for SUI patients is highest, to decrease urinary leakage [25]. Thus, with changes in PFM power, the mechanism of urethral closure and SUI improves during ultra-short pad tests and impact activities [7, 20]. Moreover, the pudendal nerve is an efferent nerve of the external urethral sphincter, so this treatment can increase the pressure of urethral closure, thus improving SUI [7].

The main limitation of this study was the absence of an electromyographic evaluation to verify changes in PFM activation. Another limitation was that we did not utilize ultrasonography to evaluate whether PFM hypertrophy occurs after ES treatment.

## Conclusions

SESSP could be considered for SUI patients, to improve QOL, urinary leakage, and PFM functions. SESSP using EasyK7 opens up new possibilities for additional studies, which should include a follow-up session, urodynamic examination, and evaluation of changes in PFM thickness and volume, and in muscle activity (assessed using sonography and electromyography), to confirm the efficacy of SESSP.

## Abbreviations

CI	Confidence interval
ES	Electrical stimulation
I-QOL	Incontinence Quality of Life Questionnaire
PFM	Pelvic floor muscle
PFMT	Pelvic floor muscle training
QOL	Quality of life
SESSP	Surface electrical stimulation in a seated position
SUI	Stress urinary incontinence
TRMP	Time to reach maximal pressure

## Declarations

### Ethics approval and consent to participate

The present study was approved by the Institutional Review Board of Yonsei University, Wonju, Republic of Korea (1041849-201806-BM-056-01).

### Consent to publish

In present study, using consent for publication was obtained from participants to publish potentially identifying details.

### Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

### Competing Interests

The authors declare that they have no potential conflicts of interest with respect to the research, authorship, and publication of this article. The results are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.

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### Author contribution

UJH, OYK made contributions to conception, design and analysis of the study and revised the manuscript. SHJ drafted the manuscript and performed the statistical analysis. MSL, YSK participated in the design of the study and acquisition of data. All authors read and approved the final manuscript.

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## Tables

Table 1. Characteristics of the participants.

	Control group (n = 16)	SESSP group (n = 17)	p value
Age (y)	41.1 ± 7.2	42.1 ± 8.8	0.726
BMI (kg/m <sup>2</sup> )	22.8 ± 3.5	22.6 ± 2.7	0.869
Duration of symptoms (y)	7.8 ± 6.0	5.9 ± 3.6	0.229
Deliveries (n)	1.5 ± 0.9	1.8 ± 0.8	0.385
Vaginal deliveries (n)	1.5 ± 0.9	1.4 ± 1.0	0.799
Ingelman-Sundberg scale score	1.4 ± 0.6	1.2 ± 0.4	0.277

SESSP, surface electrical stimulation in a seated position; BMI, body mass index

Table 2. Primary outcomes in both groups before and after the intervention.

Primary outcomes			Pre		Post		Mean change (95% CI)		Effect size	Within <i>P</i> value
IQOL	Avoidance and limiting behaviors	Control group	58.984 ± 24.390		57.031 ± 25.091	1.953	( -0.142 to 4.048 )	0.473	0.000	
		SESSP group	45.037 ± 24.633		71.691 ± 21.888	-26.654	( -36.850 to -16.459 )			
	Psychosocial impacts	Control group	56.771 ± 27.404		56.250 ± 28.191	0.521	( -1.588 to 2.629 )	0.430	0.000	
		SESSP group	47.549 ± 28.292		76.797 ± 23.260	-29.248	( -42.799 to -15.698 )			
	Social embarrassment	Control group	45.000 ± 28.868		44.063 ± 29.224	0.938	( -0.512 to 2.387 )	0.388	0.000	
		SESSP group	32.941 ± 30.262		66.471 ± 28.105	-33.529	( -50.357 to -16.702 )			
	Total score	Control group	63.864 ± 20.308		62.841 ± 21.130	1.023	( -0.288 to 2.333 )	0.449	0.000	
		SESSP group	54.652 ± 20.578		78.075 ± 18.323	-23.422	( -33.343 to -13.502 )			
Pad weight		Control group	9.358 ± 8.752		10.737 ± 8.880	-1.379	( -2.235 to -0.522 )	0.540	0.000	
		SESSP group	18.734 ± 23.619		5.371 ± 9.063	13.363	( 4.394 to 22.333 )			
PFM functions	TRMP (s)	Control group	1.438 ± 0.807		1.383 ± 0.481	0.055	( -0.399 to 0.508 )	0.185	0.014	
		SESSP group	1.368 ± 0.574		0.993 ± 0.469	0.375	( 0.048 to 0.702 )			
	Power (mmHg/s)	Control group	16.411 ± 13.202		15.156 ± 10.065	1.255	( -1.956 to 4.466 )	0.270	0.002	
		SESSP group	15.998 ± 8.982		32.032 ± 18.141	-16.034	( -24.811 to -7.257 )			
	Strength (mmHg)	Control group	18.699 ± 10.071		19.019 ± 9.403	-0.321	( -1.460 to 0.818 )	0.168	0.020	
		SESSP group	20.306 ± 8.809		26.307 ± 11.800	-6.001	( -11.201 to -0.800 )			
	Endurance (mmHg)	Control group	13.716 ± 7.963		13.268 ± 7.347	0.449	( -2.017 to 2.915 )	0.162	0.023	
		SESSP group	14.794 ± 7.116		21.118 ± 10.373	-6.325	( -10.852 to -1.798 )			

SESSP, surface electrical stimulation in a seated position; CI, confidence interval; I-QOL, Incontinence Quality of Life Questionnaire; PFM, pelvic floor muscle; TRMP, time to reach maximal pressure

## Figures



Figure 1

Flow diagram of our randomized trial in women with stress urinary incontinence



Figure 2

Surface electrical stimulation in a seated position using the EasyK7 device (Alphamedic Co., Ltd.).

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [statisticallyanalysisfile.xlsx](#)

- [CONSORT2010ChecklistMSWord.doc](#)