

## Clinical Study

# Impact of Sacral Surface Therapeutic Electrical Stimulation on Early Recovery of Urinary Continence after Radical Retropubic Prostatectomy: A Pilot Study

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*Objectives.* To investigate whether sacral surface therapeutic electrical stimulation (SSTES) initiated during the early postoperative period would be effective towards early recovery of postprostatectomy urinary continence. *Methods.* A total of 35 consecutive patients who underwent radical prostatectomy by a single surgeon were enrolled in this study. Twenty early patients began pelvic floor muscle exercise (PME). Fifteen subsequent patients received SSTES postoperatively with no instruction for PME provided. Immediate urinary function just after catheter removal was evaluated with frequency-volume chart and 24-hour pad test. *Results.* There were no differences between the SSTES and PME groups in maximum voided volume capacity (MVV) and urine loss ratio (ULR) on the first day after removal of urethral catheter. However, on day 3 MVV was significantly larger and ULR was also significantly lower in the SSTES group. *Conclusions.* SSTES treatment is feasible and appears to be effective for early recovery of urinary continence after radical prostatectomy.

## 1. Introduction

Urinary incontinence and sexual dysfunction are representative long-term complications of radical prostatectomy. During several months after radical prostatectomy, urinary incontinence develops in most patients, significantly lowering their quality of life (QOL). One year after the surgery, the incidence of urinary incontinence, the ratio of patients who require pads, and the ratio of those who experience urinary incontinence, even if only slightly, reach 5%–15%, 33%, and 66%, respectively [1, 2]. The main mechanism of postprostatectomy incontinence is considered to be damage of the sphincter muscle caused upon separation of the prostate and urethra. It has been clarified in recent years that preservation of the neurovascular bundle could be involved in the recovery of urinary continence [3], and thus a neurogenic mechanism for the sphincter muscle was indicated. In addition, detrusor overactivity can develop as a consequence of traction of the bladder. It has been reported

that urinary incontinence related to detrusor overactivity occurs in 40% and detrusor overactivity incontinence occurs in 13% of patients after radical prostatectomy [4]. To improve the postoperative urinary continence, we should consider not only urinary sphincter muscle damage but also bladder-related factors.

Pelvic floor exercise (PME) has been widely performed after radical prostatectomy with the aim of the prevention and treatment of urinary incontinence. The effectiveness of the PME depends on its instruction method, and recent reports have suggested that the effectiveness would become higher by using the preoperative biofeedback method [5].

Neuromodulation, using electrical or magnetic stimulation, was developed for urgency incontinence as well as stress incontinence [6]. These methods were used to treat postprostatectomy incontinence (PPI) [7–10]. A certain effect was observed in these studies, while these studies were applied only for patients with urinary incontinence. We developed sacral surface therapeutic electrical stimulation

(SSTES) as a therapy for urinary incontinence using neuromodulation [11]. In this therapy, skin surface electrodes are applied on the sacral surface to provide stimulation, making the treatment very easy to perform. It has been shown that SSTES has not only an inhibitory effect on detrusor overactivity but also an efferent stimulant effect to the pudendal nerve [11]. It is thus expected that SSTES initiated in an early postoperative period would be effective for early recovery of postoperative urinary continence.

## 2. Materials and Methods

The study population consisted of 40 consecutive patients who underwent retropubic radical prostatectomy for newly-diagnosed, clinically localized prostate cancer from November 2004 to November 2006. All of the operations were performed by a single surgeon (Y.A.) and technical modifications were not made except smaller skin incision during the study period. This surgeon experienced more than 500 radical retropubic prostatectomy procedures over 20 years. The patients with prolonged indwelling urethral catheter due to anastomotic leakage (two cases) and who required reinsertion of the urethral catheter because of transient dysuria (one case) were excluded from the study, since the long duration of the indwelling urethral catheter might affect the immediate continence postcatheter removal. The patients who could not complete the frequency volume chart (one case) and withdrew his consent for the use of the SSTES (one case) were also excluded. Thus, a total of 35 patients were enrolled in the study. Among them, 20 early patients (from November 2004 to December 2005) received instruction for the PME and began the exercise one day before the surgery and continued for 1 week or longer. Fifteen subsequent patients (from January 2006 to November 2006) received SSTES, which was started at postoperative day 1 with no PME instruction provided. None of the patients were prescribed anticholinergic drugs during this study. For SSTES, the stimulator was specially designed for this purpose (Nodoka, Lintec Co. Ltd., Tokyo, Japan) (Figure 1), and a pair of specially designed plate electrodes with a contact surface 4-cm  $\times$  9-cm (width  $\times$  height; Electrode type A, Lintec, Tokyo, Japan) (Figure 1) were placed symmetrically on the skin surface over the second through fourth posterior sacral foramina. Pulses of 30-Hz frequency at 200- $\mu$ s pulse width and maximum output of 80 V were used for 15 minutes twice a day for 1 week. Intensity was controlled by each patient below the pain threshold. The urethral catheter was removed on day 5 or 6 postsurgery. Immediate urinary function just after catheter removal was evaluated with a daily frequency-volume chart and 24-hour pad test. The urine loss ratio [12] was defined as the weight of urine loss in the pad divided by the daily urine volume, that is, micturition volume plus incontinence volume. The maximum voided volume (MVV) was defined as largest voided volume during single micturition from daily frequency-volume chart. The Ethics Committee of the Tohoku University School of Medicine approved this study and informed consent was obtained from all of the patients. Statistical software (JMP Statistical

Discovery Software, SAS Institute, Cary, NC, USA) was used for all analyses. Tested groups were compared by unpaired Student's *t*-test; *P*-values < .05 were considered statistically significant.

## 3. Results

Table 1 presents the patient demographics and pathological characteristics. There were no significant differences in any of the baseline clinical or pathological parameters between the two groups: age, PSA, tumor stage, biopsy Gleason score, or degree of nerve preservation. No differences were observed in any of the postoperative parameters: operative time, estimated blood loss, prostate weight, pathological stage, or positive surgical margin status. During hospitalization, each group received the scheduled PME or SSTES treatment, respectively, under the instruction of the nursing staff. One patient in the SSTES group, who experienced sinus tachycardia and discomfort during electrical stimulation, with a fever of 38 degrees centigrade and expressed a desire to stop electrical stimulation, was excluded from the analysis.

On the first day after removal of the urethral catheter, there were no significant differences between the SSTES and PME groups in maximum voided volume ( $229.3 \pm 79.2$  ml (mean  $\pm$  standard deviation) versus  $217.4 \pm 99.5$  ml, resp.; *P* = .35) or urine loss ratio ( $13.8 \pm 19.9\%$  versus  $14.5 \pm 23.7\%$ , resp.; *P* = .46). However, the maximum voided volume and urine loss ratio were rapidly improved in the SSTES group (Figures 2 and 3). On the third day after removal of the urethral catheter, the maximum bladder capacity was significantly larger in the SSTES group than in the PME group ( $315.0 \pm 59.9$  ml versus  $268.1 \pm 94.6$  ml, resp.; *P* < .05). Urine loss ratio was also significantly lower in the SSTES group ( $1.18 \pm 1.36\%$  versus  $10.32 \pm 22.7\%$ , *P* < .05). During the study period, there were no significant adverse effects observed, except for the one case described above. No patients showed the symptom of difficulty on urination. No patients complained dysuria or urinary retention during the hospital stay.

## 4. Discussion

In the literature, urinary incontinence is one cause of lowering the quality of life for patients following radical prostatectomy. Many efforts, including neuromodulation, have been made to achieve early urinary continence. Yokoyama et al. reported that extracorporeal magnetic stimulation improved continence in 60% of patients with PPI [9, 10]. On the other hand, two randomized control studies failed to show an additional effect of neuromodulation for PPI compared with PME alone [7, 8]. In these studies, electrical stimulation was applied with an anal surface electrode and was initiated after urethral catheter removal. Furthermore, in all of the studies noted above, neuromodulatory stimulation was applied in patients with existing urinary incontinence. It is well known that early rehabilitation has an advantage for early and

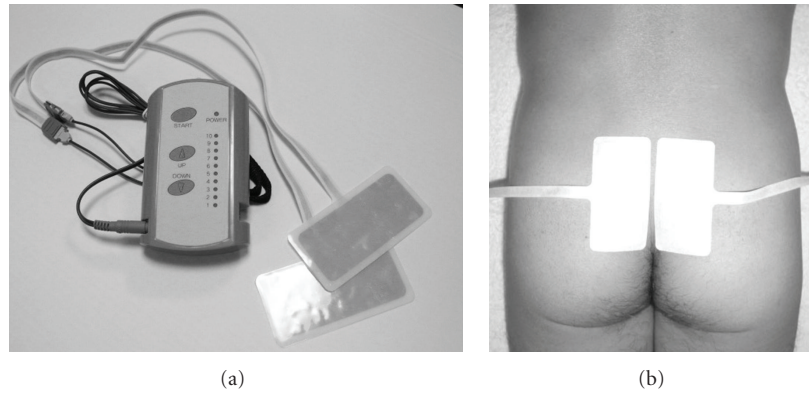


FIGURE 1: Portable electrical stimulator (Nodoka, Lintec Co. Ltd., Tokyo, Japan) and a pair of the specially-designed electrodes. A pair of electrodes was placed symmetrically on the skin surface over the second through fourth posterior sacral foramina.

TABLE 1: The demographic and clinical characteristics of the patient population.

	PFE ( $n = 20$ )	SS- TES ( $n = 15$ )	$P^*$
Age (year)	$63.1 \pm 6.4$	$61.4 \pm 6.6$	.46
PSA	$10.7 \pm 9.1$	$9.8 \pm 6.6$	.72
Clinical stage			
T1	70%	80%	
T2	15%	13%	
T3	15%	7%	.72 c
Biopsy Gleason sum			
6	5%	7%	
7	85%	86%	
8	5%	7%	
9	5%	0%	.84 c
Nerve sparing			
No nerve sparing	10%	13%	
Unilateral	50%	33%	
Bilateral	40%	53%	.62 c
Operation time	$221 \pm 66$	$226 \pm 71$	.85
Blood loss	$1170 \pm 721$	$838 \pm 360$	.11
Prostate weight	$59.7 \pm 30.1$	$45.1 \pm 12.8$	.09
Pathological stage			
pT2	80%	77%	
pT3	20%	23%	.74 c
Positive margin	20%	13%	.60 c

c: Chi-square test.

\*Unpaired  $t$ -test unless otherwise noted.

satisfactory functional recovery in nonurological fields, such as orthopedics [13], cardiac surgery [14], neurosurgery [15], and spinal cord trauma [16]. PPI occurs due to surgical damage of the urethral sphincter, pelvic floor muscle, and bladder. From this perspective, we generated the idea of initiating electrical stimulation on the first day after radical prostatectomy. As a result of this early electrical rehabilitation, significant effects on early recovery of continence and maximum voided volume were observed. To our knowledge, this is the first report on the possible rehabilitative role of neuromodulation for PPI.

The present study showed the possible utility of SSTES for early recovery of urinary function following radical prostatectomy. We previously shown that postcatheter removal incontinence is significantly related to postoperative urinary function after radical prostatectomy [17]. Therefore, it is expected that minimizing the postcatheter removal incontinence could ultimately affect the postoperative urinary quality of life. In this study, on the first day after catheter removal, there were no differences in maximum voided volume or urine loss ratio between the SSTES and PME groups. On the other hand, on the third day after

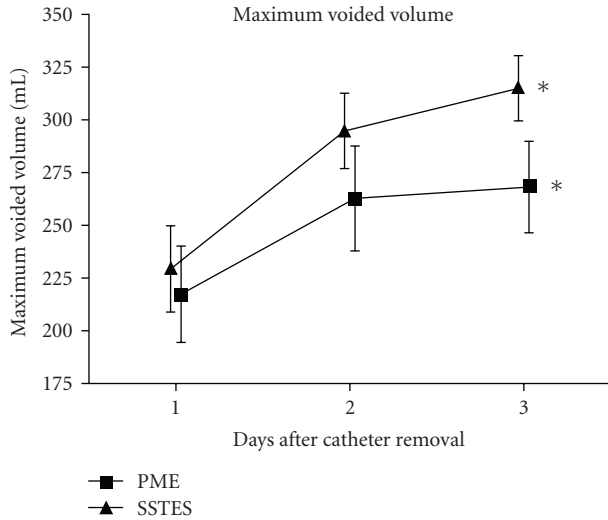


FIGURE 2: Maximum voided volume at day 1, 2, and 3 after removal of the urethral catheter. Error bars represent SEs. \* $P < .05$ .

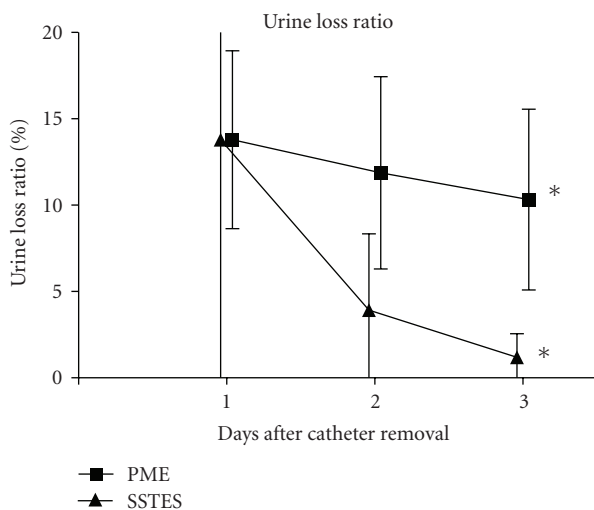


FIGURE 3: Percentage of urine loss ratio at day 1, 2, and 3 after removal of the urethral catheter. The urine loss ratio was defined as the weight of urine loss in the pad divided by the daily urine volume. Error bars represent SEs. \* $P < .05$ .

catheter removal, the maximum voided volume and urine loss ratio rapidly improved with SSTES.

It has been reported that SSTES exhibits not only an inhibitory effect on detrusor overactivity but also an efferent stimulant effect via the pudendal nerve [11]. The effect may be partly due to decreasing urgency with electrical stimulation [18]. Pelliccioni and scarpino reported the external anal sphincter response with S3 surface electrical stimulation [19]. Indeed, we macroscopically observed that contraction of the pelvic floor muscle including the urethral sphincter and levator muscle was synchronized with SSTES during open radical prostatectomy (data not shown). The efferent effect on the pudendal nerve, which is equivalent

to the effect of pelvic floor muscle exercise, and the afferent inhibitory effect can be expected for injured pelvic floor muscle and detrusor overactivity that develops after radical prostatectomy. Based on the results of this study, SSTES appears to have an early rehabilitative role on postprostatectomy urinary function.

We acknowledge several limitations in this pilot study. First, our study had relatively few patients. Second, although there was no statistical difference, the prostate volume and blood loss were smaller in the SSTES group, which may have influenced the results. Third, the study was not performed in a randomized fashion but as a historical control study. However, all operations were performed by a single, well-experienced surgeon and technical modifications were not made during the study that might minimize the intraoperator's bias, such as a learning effect. Fourth, one of the drawbacks of the neuromodulatory approach is the short carry-over effect. It is unknown whether 1-week of electrical stimulation could affect the recovery of urinary function for 1 month or longer after surgery. Indeed, it was difficult to accurately evaluate urine loss ratio using the 24-hour pad test on an outpatient basis. In the present pilot study, the optimal duration of SSTES remains to be elucidated. Nevertheless, the results show the possible rehabilitative role of SSTES in the early phase of recovery of urinary function following radical prostatectomy.

A multi-institutional, randomized controlled study with a large number of subjects is now on going.

## 5. Conclusion

We investigated the rehabilitative role of SSTES for recovery of urinary function following radical prostatectomy. This treatment is feasible and appears to be effective for early recovery of urinary continence after surgery. A randomized controlled trial with a large study population is warranted to confirm its effectiveness.

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