

## EFFECTIVENESS OF PERINOMETER BIOFEEDBACK PELVIC FLOOR MUSCLE EXERCISER WITH EXT-101TM IN FEMALE STRESS URINARY INCONTINENCE

### Hypothesis / aims of study

ExTT-101 is a newly developed device suitable for effective pelvic floor muscle exercise by doing biofeedback training with probe, headphone and LCD monitor. The recommendation is that pelvic floor muscle training (PFMT) is first-line therapy for SUI, but it is debatable if this happens in practice. The majority of females are not confident that they are performing PFMT exercises correctly and discontinued PFMT exercise due to lack of motivation. Therefore we investigated the women with SUI encouraged developing sufficient strength to contract their pelvic muscles sufficiently to prevent stress episodes by using self helping biofeedback ExTT-101 program .

### Study design, materials and methods

Sixty patients with urinary incontinence were randomly assigned to receive either biofeedback assisted-pelvic muscle training or pelvic floor muscle training (PFMT) alone. For ExTT group, the pelvic floor muscle exercise were performed by following the voice from the headphone until pumping comfortable degree of air into the probe. The treatment sessions were for 20 minutes, twice per day, five times a week, for 6 months. For the control group, only pelvic floor muscle exercises were performed as same duration. The amount of urinary leakage according to the 1-hour pad test, the number of leakage event per 7 days, questionnaire, pelvic floor muscle strength and contraction holding period were evaluated.

### Results

After 6-week of biofeedback therapy, the contraction pressure in biofeedback group was significantly increased from 17.0±4.3 to 30.7±5.4mmHg and higher compared to PFMT group ( $R^2=0.47$ ,  $p=0.000$ , 95% CI, 13.44-25.63). The contraction holding period was also significantly increased from 3.5±0.7 to 10.9±1.2 second and longer compared to PXMT group ( $R^2=0.18$ ,  $p=0.000$ , 95% CI, 7.70-13.97). No significant differences were at the 6 months detected in the PFMT group in the number of leakage event per 7 days, ICIQ-SF, KHQ scores, significant differences were detected in the biofeedback assisted group.

### Interpretation of results

The results of this study show that biofeedback-assisted training enhanced the outcomes of PFMT for stress incontinence in women. It is possible that biofeedback enhances outcomes by helping women to identify control, strength, endurance, power of their pelvic floor muscles.

### Concluding message

These results suggest that pelvic floor muscle exercise using biofeedback is more effective than PFMT and ExTT-101 may be useful medical device for measuring the contraction pressure of the pelvic muscles and treating urinary incontinence.

Table1. Clinical outcomes by treatment group at 6 week and 6 months of follow-up.

Variables	PFMT (n=24)			Biofeedback (n=30)		
	Baseline	6-week	6-month	Baseline	6-week	6-month
Voiding diary 7 days/leakages	9.7±3.3	5.8±2.6*	8.0±3.2	8.6±4.0	5.6±3.6 <sup>†</sup>	5.1±4.6 <sup>†</sup>
ICIQ-SF (median, range)	8.8±4.7	6.5±1.9*	8.2±5.1	9.0±3.9	5.4±3.8 <sup>‡</sup>	7.0±2.7*
KHQ score	68.4±15.9	44.8±11.3*	59.2±19.9	69.5±14.2	37.6±13.3 <sup>‡</sup>	48.7±12.3 <sup>†</sup>
Subjective satisfaction rate No (%)	NA	11(45.8)	6(25.0)	NA	23(76.6)	21(70)

Data presented as means ± SD or frequency (percentage). NA: not available, ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form, KHQ : King's Health Questionnaires. \* $p<0.05$ , <sup>†</sup> $<0.01$ , <sup>‡</sup> $<0.001$  vs baseline

### References

1. Neurourol Urodyn 2003; 22(4):284-295
2. Int Urogynecol J Pelvic Floor Dysfunct 2004;15:76-84

### Disclosures

**Funding:** none **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** This study was approved by the Chungnam National University Hospital institutional review board, and all participants signed informed consent forms . CNUH 2011-3453 **Helsinki:** Yes **Informed Consent:** Yes