POSTER NO. 235

Novel External Electrical Muscle Stimulation Device For The Treatment Of Female Stress Urinary Incontinence: Randomized Controlled Noninferiority Trial Versus Intravaginal Electrical Stimulation

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INTRODUCTION

Most electrical muscle stimulation devices for the treatment of stress urinary incontinence use transvaginal electrical stimulation. INNOVO® is a novel, non-invasive, external electrical muscle stimulation device for the treatment of incontinence.

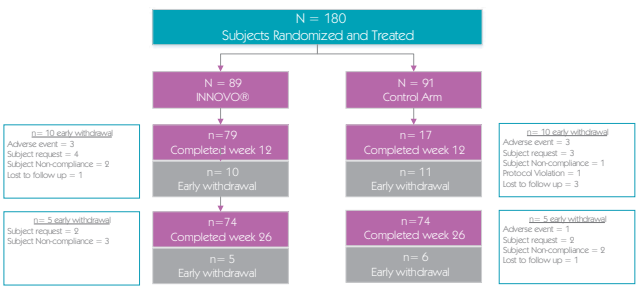
The aim of this study was to compare the efficacy and safety of the INNOVO® external electrical muscle stimulation device with an FDA-cleared intravaginal device (itouch sure) for the treatment of stress urinary incontinence in women

OBJECTIVE

A prospective, randomized, single-blind, multicenter, noninferiority study performed at 12 sites in the USA. Women with predominant stress urinary incontinence whose condition had not improved using pelvic floor muscle training were randomized to undergo treatment with either an INNOVO® or control device for 12 weeks.

METHODS

Treatment was administered by the subjects at home using the device in accordance with the relevant instructions for use, which specified that the INNOVO® device was used for 30 minutes once daily for 5 days/week, and the control device was used for 20 minutes once daily every day.



PRIMARY ENDPOINT

Proportion of subjects who achieved "significant improvement" (>50% reduction in pad weight from baseline) in the provocative pad weight test at 12 weeks

KEY SECONDARY EFFICACY ENDPOINTS

- Provocative pad weight test - urine leakage
- 24-hour pad weight test - urine leakage
- Incontinence episodes/day
- Incontinence Quality of Life questionnaire (total score)
- Pads used/day
- Dryness (<1g leakage on provocative pad weight test)

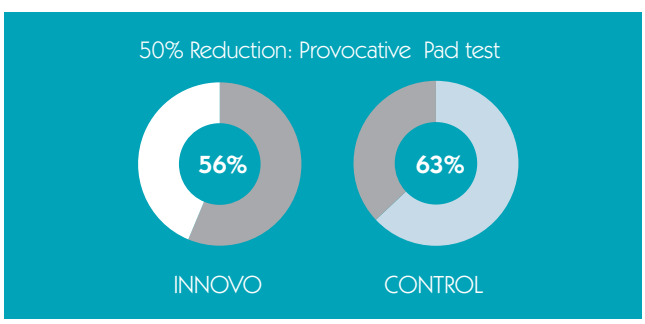
Table 1: **Primary and secondary endpoints.**

These endpoints (Table 1) were to be analysed in hierarchical fashion, provided the primary endpoint was met. Safety and tolerability were also assessed.

The study sample size was 180 patients: assuming a success rate of 52% for the control group[1] and 71% for the INNOVO®, 87 subjects/group provided 90% power using a one-sided type I error rate of 0.025 and a noninferiority margin of 5%.

RESULTS

Between April 2015 and April 2017, 89 women were randomized into the INNOVO® group and 91 to the control group. Baseline incontinence characteristics were similar between the groups



PRIMARY ENDPOINT

At week 12 a "significant improvement" in the provocative pad weight test was seen in most subjects in both the INNOVO® group (56.3%) and the control group (63.0%), although noninferiority was not established because the lower bound of the 95% confidence interval for the treatment difference did not exceed the -5% noninferiority margin (difference -6.7%, 95% CI -21.7% to 8.4%).

SECONDARY ENDPOINTS

Statistically significant improvements from baseline in mean urine leakage in the provocative pad weight test and 24-hour pad weight test, number of incontinence episodes and pads used per day, and I-QOL score were seen with both devices at week 12

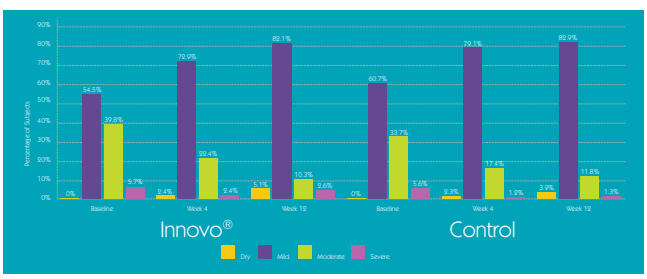
RESULTS TABLE

PARAMETER		INNOVO® (N=89)	CONTROL (N=91)
Provocative pad weight test - urine leakage	Baseline Change from baseline: week 12	24.33 (20.063) -8.48 (25.053)*	23.21 (20.448) -9.66 (22.876)***
24-hour pad weight test - urine leakage	Baseline Change from baseline: week 12	26.37 (32.204) -13.07 (21.531)***	24.74 (28.869) -9.89 (19.989)***
Incontinence episodes/day	Baseline Change from baseline: week 12	2.98 (2.341) -1.24 (1.564)***	2.93 (4.987) -1.43 (4.120)***
Incontinence Quality of Life questionnaire (total score)	Baseline Change from baseline: week 12	58.55 (19.798) 13.42 (16.463)***	59.47 (19.464) 15.42 (18.376)***
Pads used/day	Baseline Change from baseline: week 12	2.05 (1.417) -0.30 (0.998)**	1.96 (1.232) -0.44 (0.984)***
Dryness (<1g leakage on provocative pad weight test)	Baseline, n (%) Week 12, n (%)	0 (0) 17 (19.1)	0 (0) 29 (31.9)

Data are mean (standard deviation) unless indicated otherwise. * p=0.002, ** p=0.006, *** p≤0.001 vs baseline.

Table 2: **key secondary endpoints**

At week 12, 87.2% of the INNOVO® group and 86.8% of the control group were in the dry or mild categories of stress incontinence severity representing an improvement of 32.7% for INNOVO® and 26.1% for the control group .



Adverse events were predominantly mild or moderate. No serious device-related adverse events occurred. Few subjects discontinued the study due to adverse events (INNOVO® 3.4%, Control device 4.4%)

RELATED ADVERSE EVENT

Adverse Device Effects by Treatment (Safety Population)

SYSTEM ORGAN CLASS PREFERRED TERM	INNOVO® (N=89) SUBJECTS[a] N (%)	CONTROL (N=91) SUBJECTS[a] N (%)
Gastrointestinal disorders	0	1(1.1%)
General disorders and Discomfort	12(13.5%)	2(2.2%)
Infections and infestations	0	7(7.7%)
Musculoskeletal and connective tissue disorders	2(2.2%)	0
Renal and urinary disorders	2(2.2%)	0
Reproductive system and breast disorders	0	1(1.1%)
Skin and subcutaneous tissue disorders	5(5.6%)	2(2.2%)

a: Subjects experiencing multiple adverse events are only counted once within a given cell.

Table 3: **Adverse Device Effects by Treatment (Safety Population)**

CONCLUSION

The two devices provided broadly similar, clinically meaningful, improvements in a range of subjective and objective measures of stress urinary incontinence. Noninferiority versus the control group was not established for the primary endpoint, possibly in part because of underpowering. Both devices were well tolerated. INNOVO® was associated with fewer infections than the probe based control group. Compliance with treatment appeared to be better with the INNOVO®.

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REFERENCES

1. [1] Sand PK, Richardson DA, Staskin DR, Swift SE, Appell RA, Whitmore KE, Ostergard DR. Pelvic floor electrical stimulation in the treatment of genuine stress incontinence: a multicenter, placebo-controlled trial. Am J Obstet Gynecol. 1995 Jul;173(1):72-9