**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 (touch 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 at 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.

**RESULTS**
The study sample size was 180 patients: assuming a success rate of 52% for the control group[1] and 71% for 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 the I-QOL score were seen with both devices at week 12.

**RESULTS TABLE**

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>INNOVO® (N=89)</th>
<th>CONTROL (N=91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incontinence episodes/day</td>
<td>Baseline: week 12</td>
<td>Baseline: week 12</td>
</tr>
<tr>
<td>Incontinence Quality of Life questionnaire (total score)</td>
<td>Baseline: week 12</td>
<td>Baseline: week 12</td>
</tr>
<tr>
<td>Pads used/day</td>
<td>Baseline: week 12</td>
<td>Baseline: week 12</td>
</tr>
<tr>
<td>Dryness (&lt;1g leakage on provocative pad weight test)</td>
<td>Baseline, n (%)</td>
<td>Baseline, n (%)</td>
</tr>
</tbody>
</table>

**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)

**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**