

A SMART, CLOSED-LOOP, SURGERY-FREE WEARABLE BLADDER MODULATION SYSTEM WITH OBJECTIVE CONFIRMATION OF NERVE ACTIVATION USED IN THE HOME IS EASY TO USE AND CAN IMPROVE OAB SYMPTOMS IN 12 WEEKS:

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Introduction

Overactive bladder (OAB) is a stressful, disruptive disorder affecting > 16% of the adult population [1]. Symptoms of OAB cause millions of individuals to suffer with a resultant decrease in their quality of life. Several treatment options exist (behavioral therapy, oral medication, in-office or implanted neuromodulation, and onabotulinumA toxin injection), yet there are significant drawbacks to each causing utilization to remain very low.

Neuromodulation using tibial nerve stimulation is an effective therapy to treat overactive bladder (OAB). The current commercially available method used to deliver tibial nerve stimulation is via a percutaneous needle applied by a clinician in the medical office. The stimulation level and location are determined by visual confirmation of a toe twitch, while the final therapeutic level is determined by patient comfort and thus may be well below the level of a toe twitch. These methods are subjective, unreliable, and most typically done only at the beginning of a stimulation session resulting in non-standardized therapy causing variability of efficacy between patients. Using a new stimulation system design that records EMG signals from the foot in response to stimulation of the tibial nerve as a way of objectively confirming tibial nerve activation.

This study evaluated tolerability, usability, and patient satisfaction of a wearable non-invasive neuromodulation system for treating OAB that incorporates EMG as a control signal that objectively confirms nerve stimulation.



Figure 1. The surgery-free, closed-loop wearable neuromodulation system with objective confirmation of nerve activation. System includes mobile application, garment and stimulator.

Methods and Materials

This prospective feasibility study evaluated the safety and efficacy of an investigational wearable, closed-loop bladder modulation system to deliver therapy in the home and eliminate the need for a surgical implant or insertion of needle-electrodes, the “Wearable System”.

After signing the informed consent, subjects were required to demonstrate OAB symptoms on a 3-day diary and have EMG signals that could be successfully recorded with the system.

A custom-fitted garment embedded with electrodes was used to transcutaneously stimulate the tibial nerve and record EMG signals from the sole of the foot (Avation Medical, Columbus Ohio). Using a mobile application on a tablet, the clinician set the therapy parameters allowing for at-home control of the system by the subject. Enrolled subjects were instructed to use the system for a 12-week period, stimulating 3 times -per week for 30 minutes. Subjects were contacted weekly by phone and with in person evaluations at weeks 1, 4, 8, and 12. Symptom improvement was evaluated using a 3-day diary. Quality of life measurements reported elsewhere. (OM37)

Results

Twenty-one subjects enrolled in the 12-week study (1 males; 20 females). Mean age was 62 years (range 51-79). Mean duration of symptoms was 8 years (range 1-42). All subjects were able to record EMG signals. Subjects most often used positive words to describe the feeling of stimulation with the most common words being “smooth”, “tingling” and “massaging”. Most subjects (94%) found the system somewhat easy or easy to put on. Most (94%) were confident that they placed the garment correctly. Few adverse events were reported with the majority due to technical difficulties with the prototype. One patient reported pruritis due to the wearing the garment and withdrew from the study.

All Subject showed a 50% or greater improvement in one or more symptom at 12 weeks

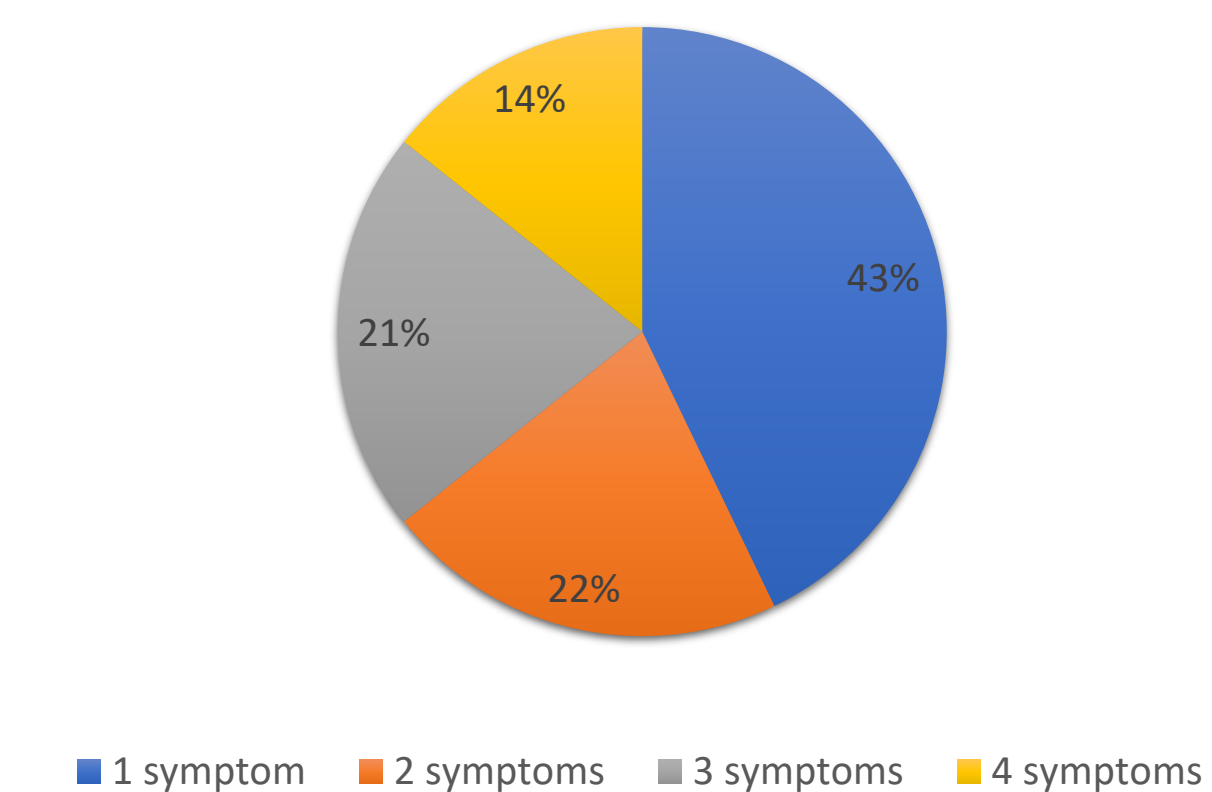


Figure 2. All subjects showed an improvement in one or more symptom of subjects who completed the diary (N=14).

Positive words were used twice as often to describe the sensation

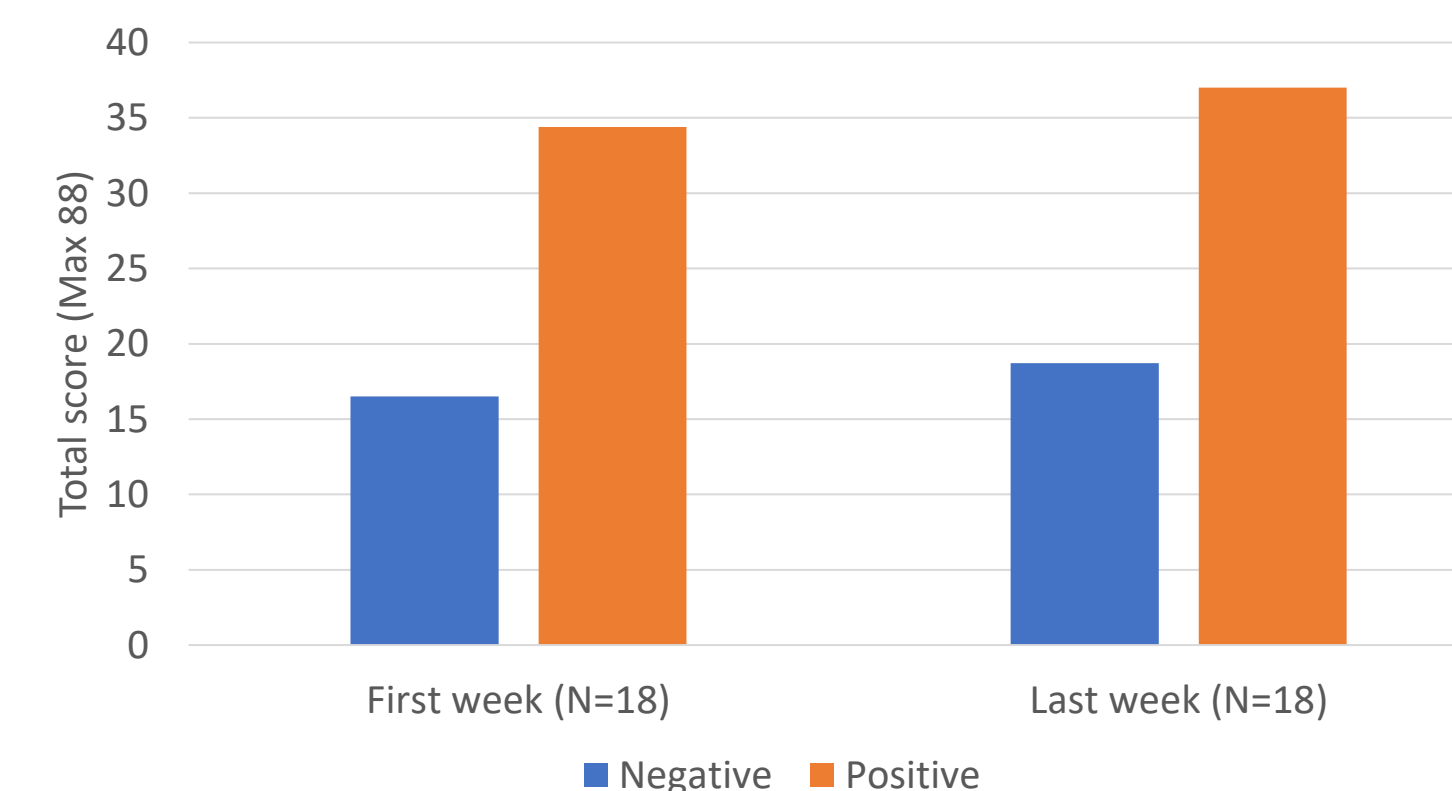


Figure 3. Graph of paresthesia descriptors comparing week 1 and week 12

Onset of Efficacy was seen at Visit 2

Visit	Daytime voids (Normal 21)	Nighttime Voids (Normal 3)	Total daily Void (Normal 24)	Urgency Events	Incontinence Events
Baseline					
Visit 2	29%	26%	27%	17%	27%
Visit 3	68%	43%	57%	30%	56%
Visit 4	89%	37%	67%	35%	43%
Visit 5	100%	48%	82%	40%	47%

Table 1 Percent improvement for each of the diary categories

Discussion

This study was performed to evaluate the safety and efficacy of an at home wearable neuromodulation system for OAB .

An earlier study provided evidence that evoked EMG from the bottom of the foot was a useful signal to not only determine the correct electrode placement but to also maintain constant stimulation. The current wearable neuromodulation system used the EMG signal to maintain stimulation throughout the therapy session. This wearable neuromodulation system is unique in that it uses an objective means of targeting and controlling stimulation during a treatment session.

We found that all subjects were able to tolerate the stimulation and found the sensation comfortable. All subjects who completed the diary showed an improvement in one or more symptom of overactive bladder. A wearable neuromodulation system for OAB may be a good alternative for patients unwilling or unable to tolerate medications or undergo invasive procedures.

Conclusions

In this small cohort, all subjects treated with the Wearable System had a 50% or greater improvement in at least one OAB symptom suggesting that a surgery-free, wearable bladder modulation system may provide an additional treatment option for patients with OAB. A larger study is needed to validate these results.

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References

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 The Avation system is an investigation device