

A Novel Wearable Neuromodulation System Using Physiologic Closed Loop Control Shows Significant Improvements in Quality of Life for OAB Patients in a Randomized Multi-center Study

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Objective

Current treatment options for overactive bladder (OAB), such as beta-3 agonists, antimuscarinic drugs, botulinum toxin injection, percutaneous tibial nerve stimulation, or surgical implants for sacral and tibial nerve stimulation are associated with drawbacks borne by patients such as side-effects, surgical risks and inconvenience, resulting in low patient adoption and adherence. There is a need for effective therapies that eliminate the side effects of medications and the risks for surgery and other invasive procedures.

This study evaluates impact of Quality of Life (QoL) for a novel, surgery-free, drug-free wearable, physiologic closed-loop tibial nerve neuromodulation device for at-home use.

Methodology

Figure 1. The Vivally System



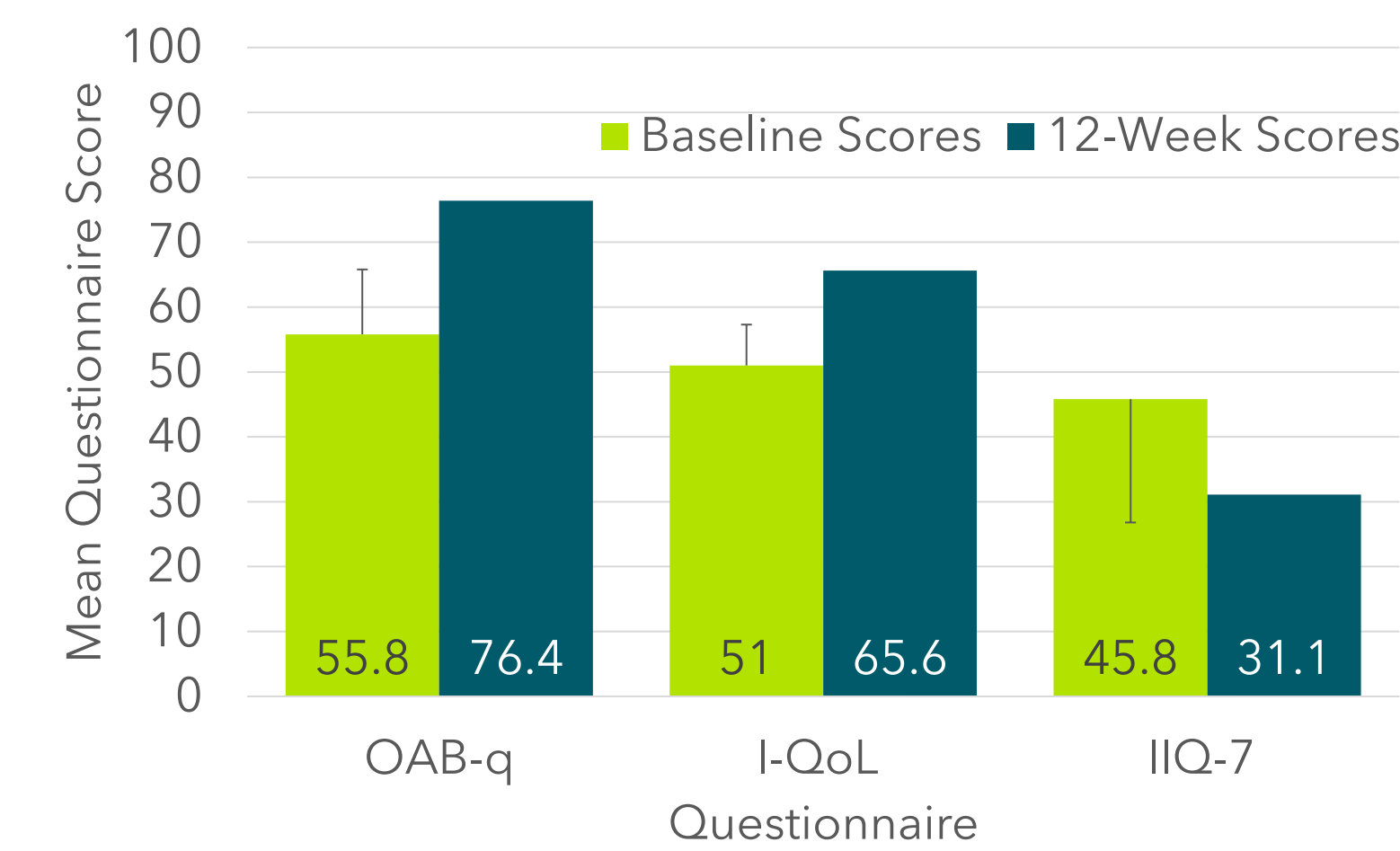
A wearable bladder neuromodulation for home use (Vivally® System) was developed by Avation Medical that lets a clinician personalize therapeutic output for each patient based on continuous EMG sensing, allowing subjects to run therapy sessions at home without clinical supervision. This physiologic closed-loop transcutaneous tibial nerve stimulation (PCL-TTNS) system was used to generate optimized and adaptive stimulation output in a randomized open-label prospective study¹ (FreeOAB) with 96 subjects, mean age 60.8 years, 88.5% female population with ≥ 10 voids/day at baseline, who conducted 30-minute therapy sessions either 1x or 3x per week.

All subjects were asked to report their OAB symptoms and 5 Quality of Life (QoL) questionnaires at baseline and after 12 weeks of treatment, with results merged between 1x and 3x therapy schedules. Of these, 3 QoL's have been validated with an established Minimal Clinically Important Difference (MCID) score. These three QoL surveys, namely Overactive Bladder Questionnaire (OAB-q), Incontinence Quality of Life (I-QoL) and Incontinence Impact Questionnaire, short form (IIQ-7) are presented here, with OAB-q further analyzed for multiple sub-categories. Results are presented for mean change in QoL, comparing with MCID, and computing the proportion of population that met certain improvement threshold.

Results

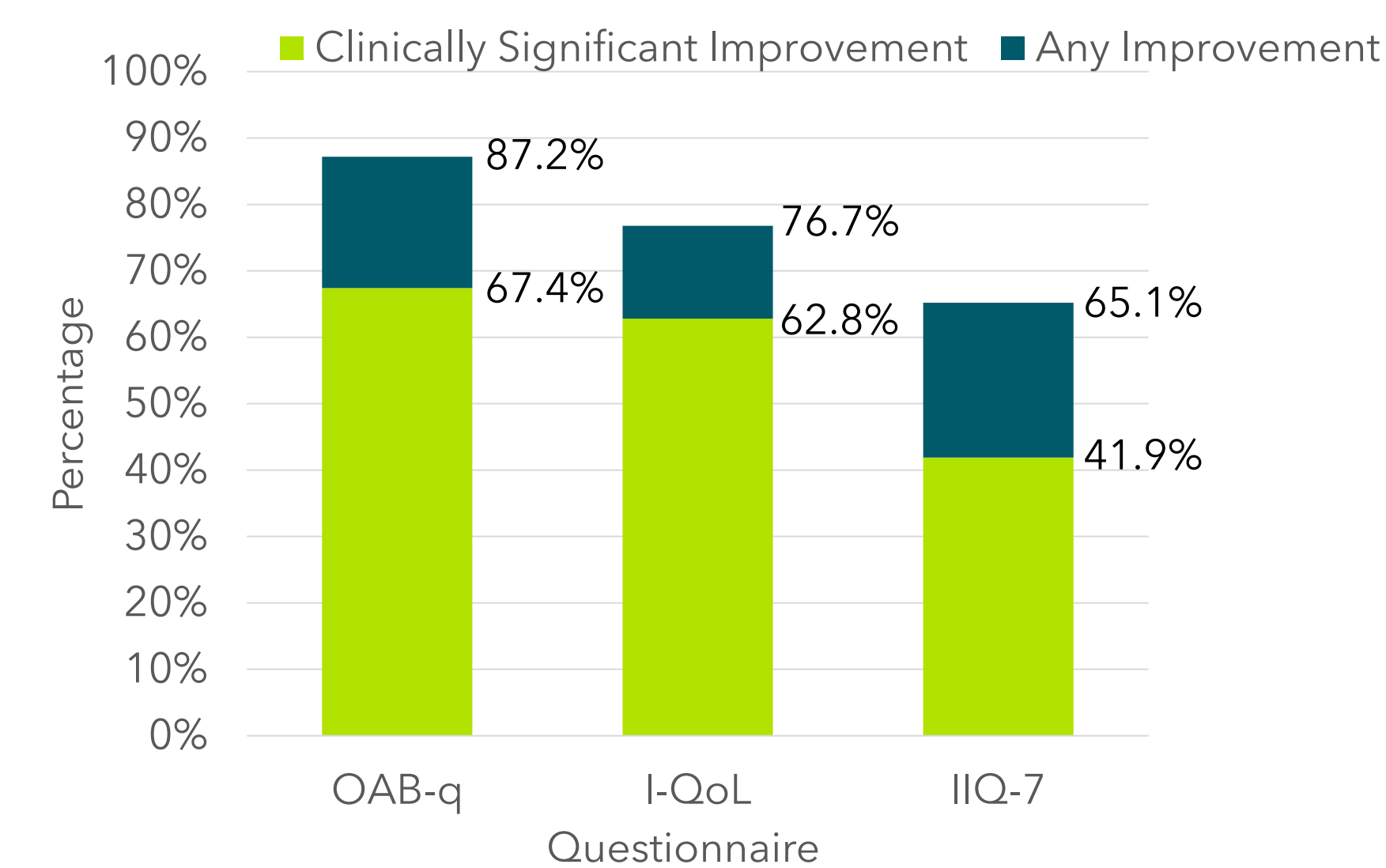
The mean QoL scores were recorded for three validated QoL metrics – OAB-q, I-QoL and IIQ-7, at baseline and after 12 weeks of therapy (Figure 2). For subjects who responded to QoL questionnaires (n=86), the improvement in mean QoL was 20.6, 14.6 and 14.7 (with $p < 0.0001$ in all cases) against the MCID²⁻⁴ of 10, 6.3 and 19, respectively. Figure 3 shows the proportion of subjects with a QoL improvement exceeding the MCID and those who showed any improvement over baseline.

Figure 2. Significant Improvement in Mean QoL Scores Compared to MCID



Population Mean QoL scores (n=86). Bars indicate MCID. For OAB-q and I-QoL a score increase indicates improvement and for IIQ-7 a score decrease indicates improvement.

Figure 3. Majority of Subjects Experienced QoL Improvement

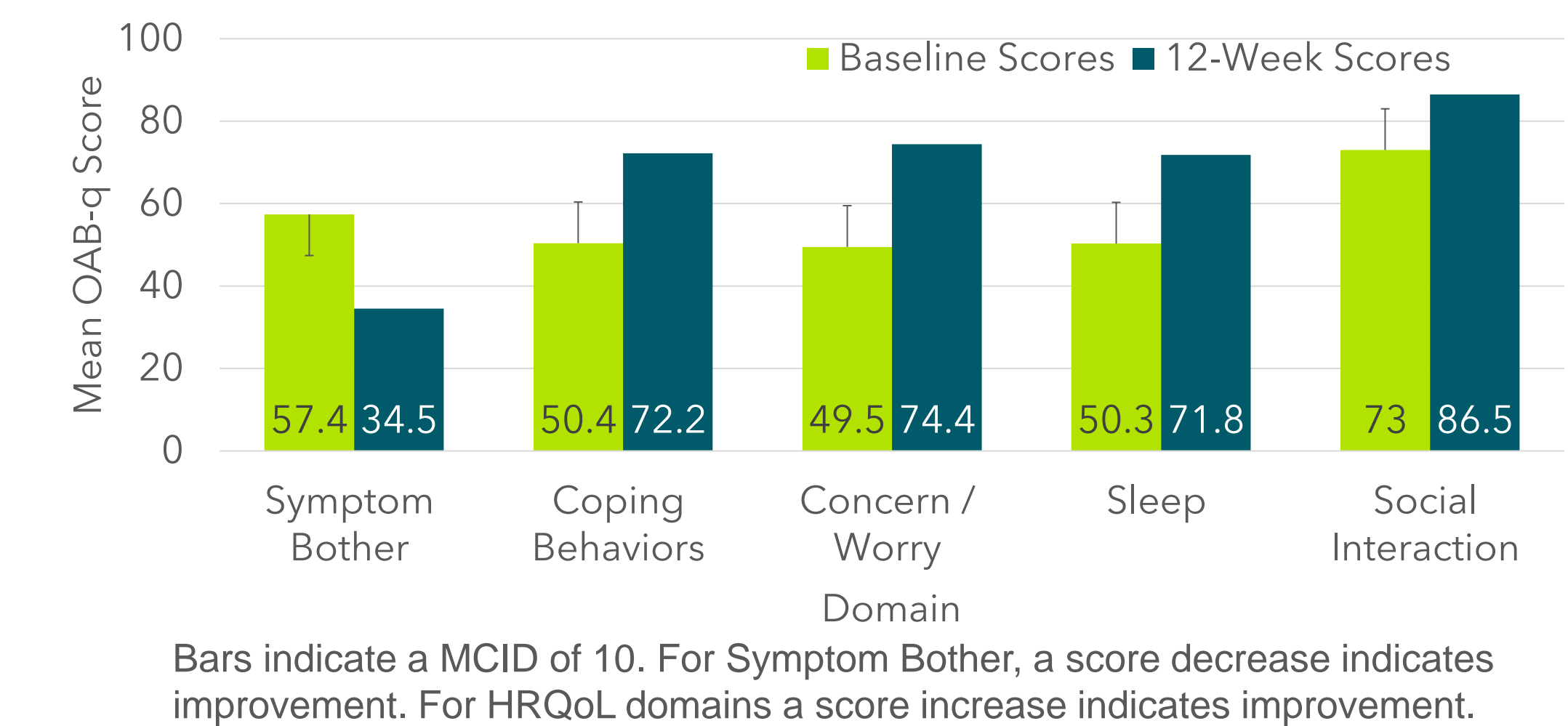


Population Percentages for QoL Score Improvements (n=86). Clinically Significant Improvement requires a 12-week score change that exceeds the MCID.

Results (continued)

Further analysis was done for OAB-q (Figure 4) that assesses bladder symptom bother (8 items) and health-related QoL (HRQoL) (25 items) on 4 domains: coping, worry/concern, sleep, and social interaction. Results show that an improvement exceeding MCID of 10 was achieved for each sub-category.

Figure 4. Mean OAB-q Subscores at 12 Weeks Exceed MCID for All Domains



Conclusion

The study demonstrated that wearable neuromodulation of tibial nerve, supplemented with physiologic closed-loop control to optimize therapeutic output, can be a safe and effective treatment of OAB, and positively impacts patients' Quality of Life. The assessments with the OAB-q, I-QoL and IIQ-7, at baseline and at 12 weeks indicated that subjects had significant and clinically meaningful improvement in their QoL as related to their OAB symptoms after use of the device.

References

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