

# Do we need more patient-friendly treatment options for overactive bladder (OAB)?

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## Abstract

**Aims:** To collect feedback from subjects diagnosed with overactive bladder (OAB) on its impact on their quality of life, their satisfaction with current treatment options, and to assess nonsurgical, tibial nerve stimulation as a treatment option.

**Methods:** Subjects were asked a variety of questions about the impact of OAB on their lives, their satisfaction with current and previous treatment approaches. Subjects evaluated the comfort of a nonworking prototype garment and were given electrical stimulation over their posterior tibial nerve to assess comfort and tolerability. Electromyographic (EMG) signals were recorded.

**Results:** A total of 40 subjects with OAB symptoms were evaluated in the study. Urgency (55%), frequency (47.5%), nocturia (40%), and incontinence (30%) were the most bothersome symptoms. At the time of the study only 32.5% of the subjects were treating their OAB symptoms. Of those that had tried and discontinued treatments, most had failed medications ( $n = 14$ ) due to no improvements or side effects. Only 2 subjects found stimulation to be uncomfortable before an EMG signal could be detected. The most common word used to describe the feeling of stimulation was “constant,” followed by “tingling,” “vibrating,” and “comfortable.”

**Conclusions:** Most subjects who had tried OAB treatments were dissatisfied and discontinued their use. A new patient-friendly approach to OAB therapy that delivers efficacy but overcomes drawbacks associated with currently available treatments is needed. Subjects found electrical stimulation over the tibial nerve to be comfortable and tolerable and this should be considered as an alternative treatment approach for OAB.

## KEYWORDS

electromyographic, medication, neuromodulation, nonsurgical, overactive bladder, patient-friendly, wearable

## 1 | INTRODUCTION

Overactive bladder (OAB) is a stressful and disruptive disorder that causes millions of individuals to suffer from a decrease in their quality of life.<sup>1</sup> OAB is defined as the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urge urinary incontinence, in the absence of urinary tract infection or other obvious pathology. Urgency is the complaint of a sudden, irresistible desire to pass urine. Frequency is the number of voids per day (>7 voids per day). Nocturia is greater than 1 void per night. Urge incontinence is the involuntary leakage of urine associated with sudden compelling desire to void.<sup>2</sup> To be diagnosed a combination of these symptoms must be present without a pathologic or metabolic component causing them.<sup>3</sup> The national prevalence of OAB is 16.5%. The real number of individuals with OAB is most likely much larger. Many people living with OAB delay or do not seek medical attention, others are embarrassed and do not know how to talk to their health care providers about their symptoms, and others are often unaware that there are treatments available for OAB.<sup>4</sup>

Patients are offered treatment following guidelines from the American Urological Association. First-line treatments are physical therapy and behavioral therapies. These can be effective, but many patients are non-compliant.<sup>5</sup> Second-line treatment are medications. Anticholinergic and  $\beta$ -3 agonist drugs show improvement rates of 70% to 80% but produce significant side effects (dry mouth, blurred vision, and cognitive decline) and can be cost-prohibitive.<sup>6</sup> Third-line therapies include intradetrusor onabotulinumtoxin (Botox) injections, and neuromodulation. Botox produces a temporary improvement in up to 70% of cases; however, may cause urinary retention.<sup>7</sup> Neuromodulation using percutaneous tibial nerve stimulation (PTNS) is up to 70% effective and has few side effects but requires frequent visits to the clinic.<sup>8</sup> Also, because it lacks an objective method of nerve location and activation, PTNS' efficacy can be highly dependent on the clinician performing the procedure. Sacral nerve stimulation (SNS), has improvement rates of 70%–75%, but is invasive<sup>9</sup> and may require additional surgeries.

Despite there being several efficacious treatments for OAB, treatment persistence remains extremely low due to the side-effects, risks, and inconvenience of the available options. There remains a compelling need for a patient-friendly treatment that is effective, economical, and adaptable to a patient's lifestyle. To determine feasibility of such an approach, this study evaluated the comfort and tolerability of noninvasive neuromodulation on patients with OAB as well as their interest in such an approach.

## 2 | MATERIALS AND METHODS

This was a prospective, single-visit feasibility study to assess a subject's interest in and feasibility of nonsurgical, neuromodulation for the treatment of OAB. The study had three aims: (1) to document the impact of OAB on the lives of the subjects, their current treatment approach, and prior experience with and preferences about treatment options; (2) to assess the design and fit of a nonfunctioning prototype garment; and (3) to assess comfort and tolerability of transcutaneous electrical stimulation of the tibial nerve (TTNS) and the ability to detect an electromyographic (EMG) signal as confirmation of nerve activation. Subjects previously diagnosed with OAB were screened based on the inclusion and exclusion criteria of the study.

After subjects met the inclusion criteria and signed the informed consent, they were enrolled in the study. Demographic and baseline measurements were collected. Quality of life was assessed using the I-QOL incontinence questionnaire, the incontinence impact questionnaire 7, and the OAB questionnaire. In addition to the standardized questionnaires, subjects were also asked about their knowledge and experience with first, second, and third line treatments and their experiences living with OAB.

After completing the questionnaires subjects were asked to put on a prototype garment (non-stimulating) and asked questions regarding the fit, comfort, appearance, and ease of use. The prototype garment was removed and the subject underwent TTNS using a variety of stimulation parameters to assess comfort and tolerability. Stimulation of the nerve was objectively assessed by recording the evoked EMG signal at the bottom of the foot. Commercial stimulation electrodes were placed over the tibial nerve at the level of the medial malleolus (1-inch Syrtenty TSYR 1000-40 round electrode; 1.57-inch  $\times$  1.18-inch oval 20PK-SNAP-SM electrode; and VERMED Neuroplus reference electrode, Figure 1A). EMG electrodes were applied to the sole of the foot to record signals in response to stimulation of the tibial nerve (Figure 1B).

An constant asymmetric waveform was applied using a commercially available transcutaneous stimulator (BIOSTIM NMS2-DIGITAL MUSCLE STIMULATOR [ESTIM]). Subjects were assessed with various pulse widths, amplitudes, and frequencies (within commercially approved levels) to find the maximum tolerable level and detect EMG. An oscilloscope was used to record the EMG signals (Hantek DSO1000 Series, BMA-200 AC/DC amplifier, and ISO-Z isolation head-stage). Following stimulation, subjects described their feeling of the stimulation and their preference for noninvasive stimulation as a treatment option for OAB.

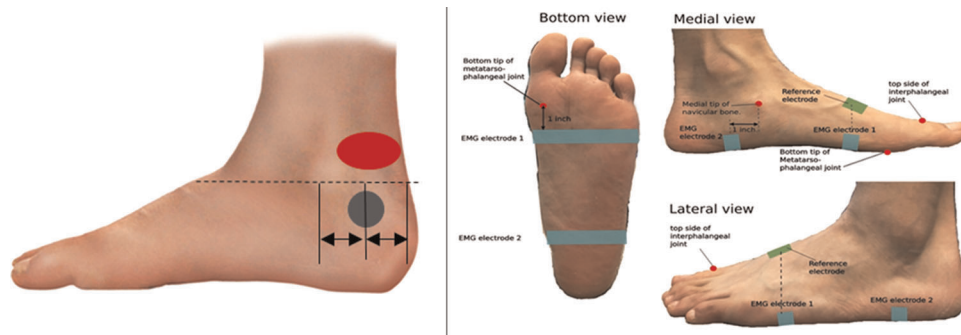


FIGURE 1 (A) Configurations and locations. Red represents the anode. Gray represents the cathode. (B) The position of the recording electrodes

### 3 | RESULTS

Forty subjects previously diagnosed with OAB were evaluated in this study. Subject demographic information is shown in Table 1.

#### 3.1 | Overactive bladder lifestyle impact and treatment history interviews

Subjects responded to open-ended questions asking about their experience living with OAB. Some subjects responded with multiple answers. Responses to the question, “What frustrates you most about having OAB?” are shown in Figure 2A. Responses to, “What do you miss about your life before being diagnosed with OAB?” are shown in Figure 2B.

At the time of the study only 32.5% of the subjects were treating their OAB symptoms. Of those, 25% used behavioral therapy, 7.5% used Kegel exercises, 10% used medications. Most subjects (57.5%) had never tried a treatment beyond first-line therapy. The mean satisfaction on a five-point Likert scale was a 3 or lower for all current therapies, (2.4 behavioral therapy, 3.0 Kegels, 2.8 medication). Only three subjects had been offered neuromodulation therapy (PTNS or SCS). Subjects who had discontinued a treatment were asked to give reasons for stopping (Figure 2C).

#### 3.2 | Stimulation

All 40 subjects received stimulation. Stimulation was increased progressively until an evoked EMG signal was detected, or until the sensation of the stimulation became intolerable. An EMG signal was detected, and stimulation found comfortable in 33 (82.5%) of the subjects. We were unable to record an EMG signal in seven subjects; in five subjects, the maximum stimulation capability of the BIOSTIM ESTIM device was reached before an

TABLE 1 Demographics of the patients enrolled in the study

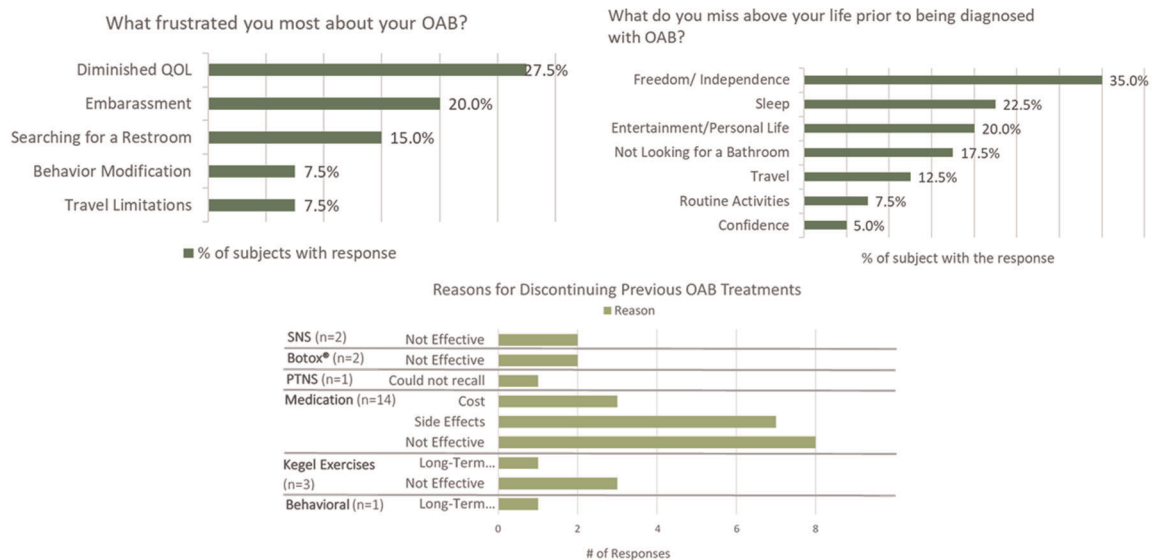
Baseline characteristics	Value	Range
Baseline participants	40	NA
Age (mean) years	58	25–73
Gender	Male: 10 Female: 30	NA NA
BMI (mean)	34.8 ± 9.11 <sup>a</sup>	
Duration of OAB symptoms (mean) years	8.6 ± 8.10	1–30
Voids per day (mean)	11.19 ± 4.44	
Urge episodes per day (mean)	5.98 ± 5.37	
Incontinent episodes per day (mean)	3.62 ± 4.68	
Nocturia episodes per day (mean)	2.50 ± 1.89	
OAB-q SF symptom score (mean) <sup>b</sup>	59.8 ± 19.5	
OAB-q SF HRQL score (mean) <sup>b</sup>	52.4 ± 18.5	
IIQ-7 score (mean)	53.1 ± 23.5	
Most bothersome symptom, %	Urge Nocturia Frequency Incontinence	39% 25% 19% 18%

Abbreviations: BMI, body mass index; HRQL, health related quality of life; IIQ, incontinence impact questionnaire; OAB, overactive bladder; SF, short form.

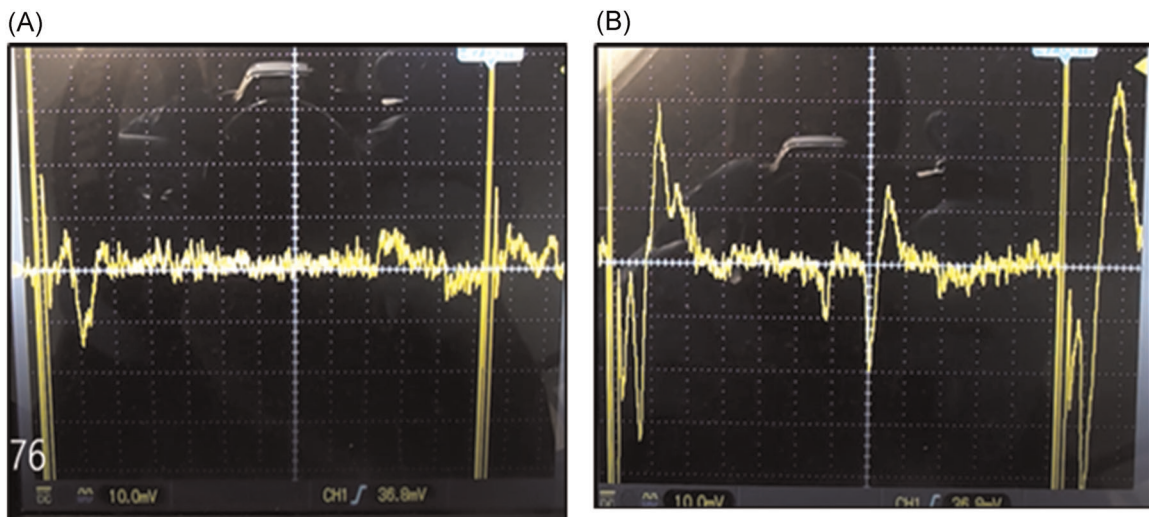
<sup>a</sup>67.35% of the patients were obese (defined as BMI > 30).

<sup>b</sup>Scores range from 0–100; higher scores indicate greater symptom bother, or better HRQL.

evoked EMG could be detected; and in two subjects stimulation was found to be uncomfortable before an EMG signal could be detected. Subjects were most likely to describe the stimulation sensation using positive descriptors. The most common word used to describe the feeling of stimulation was “constant,” followed by “tingling,” “vibrating,” and “comfortable.”



**FIGURE 2** (A) A sample of the categorized responses by subjects of what frustrated them about their OAB. Some subjects had multiple responses. (B) The categorized responses of the subjects' responses to what they miss about their life from before having OAB. Some subjects had multiple responses. (C) The reasons reported by subjects for discontinuing a previous OAB treatment. Some subjects reported multiple reasons for discontinuing a single OAB treatment. OAB, overactive bladder



**FIGURE 3** EMG recordings from the same subject at different intensity levels; (A) Stimulation at level 4.5; (B) Stimulation at level 9.0

Stimulation of the tibial nerve resulted in two EMG waves. The first wave appeared after 2–3 ms and occurred in 82.5% of subjects (Figure 3A). The second wave appeared after 60–65 ms and occurred in only 22.5% of subjects and, only at higher stimulation intensities (Figure 3B).

When asked their likelihood to try a nonsurgical, wearable neuromodulation system, on a five-point Likert scale, 95% reported that they were very or extremely likely to try such a system. Using an open-ended questionnaire, subjects were asked to report the benefits and drawbacks they perceived for nonsurgical, wearable neuromodulation system for OAB. (Figure 4A,B).

## 4 | DISCUSSION

The intent of this study was to evaluate the treatment patterns and awareness of OAB therapies among OAB patients and to determine their interest, tolerance, and acceptability of a nonsurgical, wearable neuromodulation therapy. OAB is a major healthcare problem associated with a substantial impact on quality of life. Treatment options involve moving from first-line treatments such as lifestyle and behavioral changes, to second-line pharmacotherapies. In a recent study evaluating the persistence and adherence with

mirabegron in women with OAB, out a cohort of 80 patients only 15 continued using the treatment after 6 months.<sup>10</sup> One of the main reasons for discontinuation was the cost of the therapy. If patients fail first- and second-line treatments, they may be offered more invasive third-line therapies, such as Botox, PTNS, or surgical implantation of SNS.

A limitation of this study is that prevalence data was only collected on 40 subjects. Most subjects in this study were female and average age was 58 years. Subjects had experienced OAB symptoms on average 8 years or more, with the most bothersome symptom being urge episodes. The most common frustration was a "diminished quality" of life followed by "embarrassment". A third of subjects found that their OAB symptoms caused them to miss their freedom and independence. Despite having significant symptoms, only 32.5% of those screened were in active treatment for OAB at the time of the study. Of those who tried and then discontinued treatments, medications were the treatment discontinued most often. Discontinuation of medication was attributed to either non-effectiveness or bothersome side-effects. This data is comparable to other larger reports which have shown that only 40% of the more than 34 million adults with OAB seek treatment.<sup>11</sup> A study by Milsom, et al. found that OAB symptoms were highly prevalent, and while many subjects had actively sought medical help most dropped out of the treatment pathway over time.<sup>12</sup> Another study by Moskowitz, et al.<sup>13</sup> found that lack of awareness and education about third-line treatment options was a barrier to treatment progression in OAB patients.

Today third-line treatments for OAB include Botox and neuromodulation. The two types of neuromodulation therapies that are commercially available and have been proven to be clinically effective are PTNS and SNS. PTNS is provided in a clinic setting. A 34-gauge needle

electrode is inserted approximately 5 cm cephalad to the medial malleolus and posterior to the tibia with a surface electrode on the arch of the foot. PTNS, at a current level of 0.5–9 mA and 20 Hz, is performed initially for 30 min once a week for 12 weeks, followed by occasional treatments as needed based on patient symptoms.<sup>8</sup> SNS involves the implantation of an implantable pulse generator (IPG) and electrode lead in an operating room. Stimulation is delivered continuously to the sacral nerves.

The posterior tibial nerve is a mixed sensory-motor nerve, containing nerves that pass through the L4–S3 spinal roots. These sacral roots also contain the peripheral nerves involved in the sensory and motor control of the bladder and pelvic floor, and are the same spinal tracts targeted by sacral neuromodulation. Electrical stimulation of these nerves inhibits bladder activity by stimulating large diameter sensory afferent nerves, which, in turn evokes a central inhibition of the micturition reflex pathway in the spinal cord or the brain.

In studies that compared PTNS to drugs, PTNS showed either equivalency or superiority.<sup>14–16</sup> PTNS efficacy has also been shown to be sustained over several years.<sup>17</sup> A randomized sham controlled study (The SUMiT Trial) demonstrated PTNS superiority to sham for both objective voiding parameters and subjective patient assessments.<sup>8</sup> A systematic review of the literature evaluating the effectiveness of SNS found that patients used significantly fewer pads and had fewer incontinent episodes compared to baseline.<sup>18</sup> Although both types of neuromodulation are effective, they both come with their own drawbacks. PTNS requires the insertion of a needle and visits to a clinic making it difficult for patients to be compliant. A recent study found only 39% of subject continued maintenance therapy after 12 months.<sup>19</sup> SNS involves a complex surgical procedure that is only performed by a small group of specialists and is associated

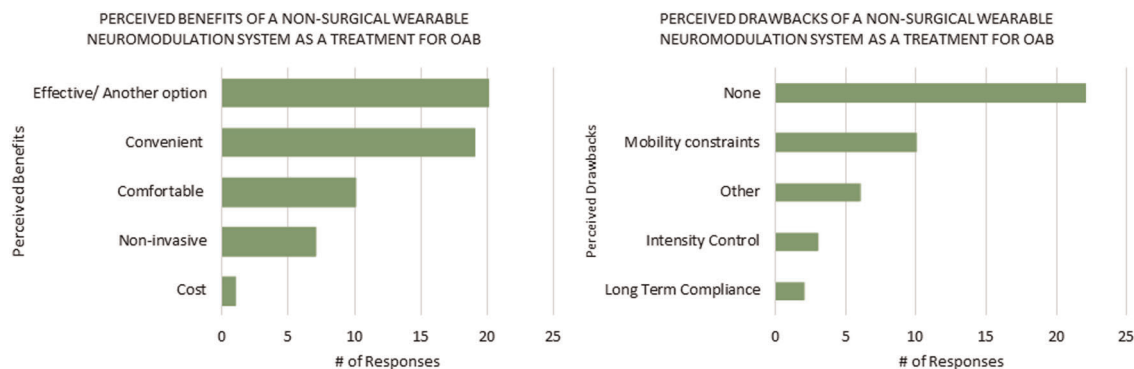


FIGURE 4 (A) The perceived benefits of a transcutaneous tibial nerve stimulation system for OAB reported by subjects. Some subjects reported multiple benefits. (B) The perceived drawbacks of a transcutaneous tibial nerve stimulation system for OAB reported by subjects. Some subjects reported multiple drawbacks. 6 unique responses were reported and is represented as "other"

with risks during the implant surgery as well as post-surgical risks including pain, infection, lead migration, and breakage, and IPG failure.<sup>18</sup> When these adverse events do occur, they often require additional surgical procedures.

While there are no head-to-head RCTs that compare PTNS and SNS, it seems reasonable that patients would first be offered PTNS, as it is office-based, less invasive, and less expensive than SNS. A study by Wooldbridge showed that PTNS can be effectively added to drug therapy, gaining additional benefit when compared to drug alone, and that PTNS may permit a lower dose of drug for equivalent.<sup>20</sup> However, the PTNS procedure itself can be inconsistently delivered between centers and between practitioners. The main variable is lack of an objective method to identify the nerve and maintain maintaining consistent stimulation throughout the 30-min treatment.

Despite wide availability and reported efficacy of all three types of third-line OAB treatments, their real-world adoption is extremely low. A study by Moskowitz, et al.<sup>13</sup> reported that in the average urology practice, the percentage of patients pursuing third-line therapies was less just 3.5%. This is widely believed to be due to patients being unaware of these options or opting not to pursue them due to potential risks, inconvenience, or treatment failure fatigue.

Recent studies have begun to explore the use of TTNS and have found similar efficacy to PTNS. TTNS involves placing electrodes on the skin over the tibial nerve. Stimulation is delivered using an external stimulator attached to the electrodes by wires. Currently, there are no commercial wearable neuromodulation systems specifically designed or FDA approved for the treatment of OAB symptoms. Several studies have reported efficacy of TTNS on OAB patients.<sup>21–23</sup> While others have shown TTNS to compare favorably to medications,<sup>24</sup> Ramírez-García et al. demonstrated non-inferiority between transcutaneous and percutaneous tibial nerve stimulation.<sup>25</sup> Another study by Martin-Garcia, et al.<sup>26</sup> that compared PTNS to a home-based stimulation system found no statistically significant difference between the two groups.

Although most of these studies involve only on a small number of patients and use TENS systems designed and approved for treatment of pain, the results are very encouraging and point to an opportunity to develop a home-based, wearable neuromodulation therapy specifically for OAB patients.

Of the 40 subjects that received stimulation in our study, nearly all, 95%, were able to tolerate the stimulation and found it comfortable. Further, there was strong interest in the concept of nonsurgical, wearable neuromodulation with 95% of the subjects indicating that they

would be very likely or extremely likely to try a non-surgical, wearable neuromodulation system at home to treat their OAB.

In addition to requiring treatment in a clinic, PTNS also lacks an objective tool to identify the tibial nerve, confirm nerve activation and maintain optimal electrode placement during therapeutic stimulation. The tibial nerve is a mixed nerve and therefore contains both sensory (afferent) and motor (efferent) nerves. We evaluated the feasibility of using the evoked EMG signal recorded on the bottom of the foot as a measure of nerve activation confirmation. EMG signals are electrical signals produced by the muscle when it is activated and is an objective indication of motor nerve stimulation. We identified two EMG waves evoked by tibial nerve stimulation at the ankle. The first wave (M-wave) was the result of the signal traveling directly to the muscles in the foot. This wave can be identified by the fact that it occurs within a few milliseconds after stimulation. We were able to record the M-wave consistently and noninvasively on 33 of the 40 subjects tested. EMG was not detected in seven subjects, of these five subjects were unable to record EMG because the TENS device could not go high enough. The remaining two subjects found the stimulation uncomfortable before an EMG signal could be detected. A second later wave was observed in 22.5% of subjects. This wave, the F-wave, was the result of the signal first traveling (antidromically) towards the spinal cord, causing a backfiring of the motor nerve. The backfiring causes the signal to travel back toward the muscles in the foot producing a second EMG signal approximately 60ms after the first one. Both signals confirm stimulation of the tibial nerve, however, the F-wave does not occur with every stimulation pulse and often requires a high stimulation pulse. We determined that the M-wave would provide a more robust signal to determine when the tibial nerve was stimulated.

## 5 | CONCLUSION

Most subjects reported that their OAB symptoms caused a decrease in quality of life. The majority also reported that they had previously tried OAB treatments but had subsequently discontinued and that they would be interested in a patient-friendly approach to OAB therapy that delivered efficacy and overcame drawbacks associated with currently available treatments. After experiencing the sensation of stimulation, most subjects found transcutaneous stimulation comfortable and 95% of the subjects reported that they would be extremely or very likely to try a surgery-free, noninvasive stimulation

system to treat their OAB. Given the high discontinuation rate of treatment options, a nonsurgical, wearable neuromodulation system may provide a viable treatment alternative. A long-term study with a system specifically designed for OAB patients is needed to determine reliability of evoked EMG signals as a detection and control method and usability, patient satisfaction, and efficacy.

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## CONFLICT OF INTERESTS

Avation Medical was the sponsor for this study. Dr. Cameron reports personal fees from Avation Medical, during the conduct of the study. Ms. LeScorzec was an employee of Avation Medical at the time of the study. Dr Zhang is an employee of Avation Medical and holds patents licensed to Avation Medical. Dr Gerig is a consultant for Avation Medical. Dr Arora and Jessica Spear are employees of Aventiv Research who performed the study and received compensation from Avation Medical.

## AUTHOR CONTRIBUTIONS

Dr. Cameron developed the protocol, reviewed the data, wrote the paper and helped to conduct the study. Ms. LeScorzec and Dr Zhang developed the protocol and conducted the study. Dr Gerig reviewed the data and wrote the paper. Dr Arora and Jessica Spear recruited the patients and conducted the study.

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