Poster-119

난치성 과민성 방광 치료를 위한 이식형 신경 자극 기술

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Implantable tibial nerve stimulation for refractory overactive bladder

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Abstract

Overactive bladder (OAB) is a chronic, progressive condition characterized by symptoms of urgency, frequency, nocturia, and incontinence. These symptoms affect millions worldwide and are associated with reduced quality of life, emotional stress, and social limitations. First- and second-line treatments, including behavioral modifications and pharmacological agents, are often poorly tolerated or ineffective. Implantable tibial nerve stimulation (iTNS) has emerged as a promising third-line option, combining neuromodulatory efficacy with a minimally invasive design. This poster synthesizes current-generation iTNS devices, their engineering innovations, regulatory progress, and clinical outcomes. Emphasis is placed on the transition toward adaptive, closed-loop technologies and the role of biomedical engineering in shaping a new standard of personalized, durable, and non-invasive OAB care.

1. Introduction

The Unmet Need in OAB Treatment

Overactive bladder is a significant global health burden, particularly affecting aging populations [1]. Despite available treatments, high discontinuation rates are reported due to poor efficacy, adverse effects, or invasive procedures. Many patients either fail to achieve symptom relief or drop out of treatment due to side effects such as dry mouth, constipation, cognitive changes, or discomfort from injectable or surgical interventions.

A New Paradigm: Implantable Tibial Nerve Stimulation

iTNS offers a less invasive alternative by targeting the posterior tibial nerve; an established gateway to modulate sacral plexus activity. Unlike conventional percutaneous tibial nerve stimulation (PTNS) requiring weekly clinic visits, implantable systems provide continuous, long-term therapy with minimal user input. These devices capitalize on decades of neuromodulation research while introducing innovations in implant design, power delivery, and automation to improve adherence and patient outcomes [2].

Current Device Landscape and Regulatory Standing

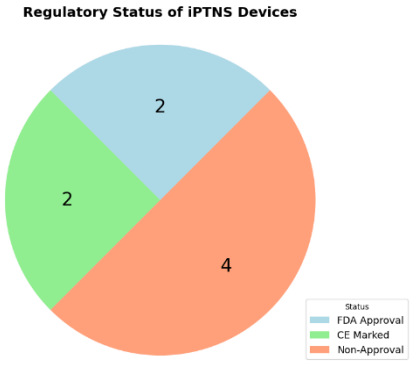

Figure 1. Regulatory Status of iTNS Devices

of 2025, seven leading iTNS devices have been developed or are under clinical investigation.

Among these; Two systems (Revi™ and eCoin™) have obtained FDA approval, demonstrating both safety and therapeutic benefit in controlled studies.

Two devices (Revi™ and StimRouter®) have received CE Mark certification, enabling commercial use in European markets.

The remaining four systems (Protect PNS™, Titan TNM, INTIBIA™, and Urgent-SQ) are in various stages of clinical trials or regulatory submission, reflecting a rapid growth in global interest and commercial viability.

These regulatory milestones underscore the maturation of iTNS as a medical device category and indicate increasing confidence in the neuromodulatory potential of tibial nerve pathways.

2. Engineering Innovations Driving iTNS Evolution

Miniaturization and Simplified Implantation

Modern iTNS devices are significantly smaller than earlier neuromodulation platforms, allowing subcutaneous implantation using local anesthesia and ultrasound guidance. Devices such as INTIBIA™ and eCoin™ leverage compact form factors to enable procedures lasting less than 30 minutes. Reduced device volume not only minimizes trauma but also enhances patient comfort and aesthetic appeal [3].

Battery-Free and Wireless Power Delivery

Several systems, like BlueWind's Revi™, operate without internal batteries by using external wearable transmitters that wirelessly power the implant through electromagnetic coupling. This reduces the risks associated with battery degradation, heating, or surgical replacement. These externally powered systems also allow patients to control therapy schedules, intensity, and duration without requiring clinic reprogramming.

Programmable and Automated Stimulation

Key engineering advancements allow for custom stimulation protocols tailored to patient response. Devices can be preprogrammed or adjusted in-clinic with variable pulse widths, amplitudes, and frequencies. In some systems, therapy can be delivered automatically throughout the day in short bursts, mimicking physiological patterns of nerve activation to prevent neural fatigue or adaptation.

3. Clinical Outcomes and Real-World Effectiveness

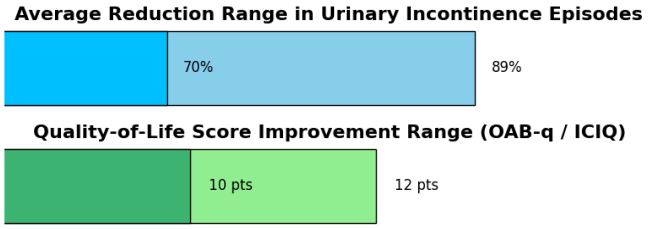

Figure 2. Average Reduction Range of UUI and OAB-q of iTNS Devices

Studies involving implantable tibial nerve stimulation systems consistently report substantial improvements in urinary incontinence control, urgency reduction, and patient satisfaction. Devices such as Revi™, Protect PNS™, and INTIBIA™ demonstrate average reductions in urgency urinary incontinence episodes ranging from 70% to 89%, depending on baseline severity and stimulation protocol.

Patient-reported quality-of-life scores using instruments such as the Overactive Bladder Questionnaire (OAB-q) or ICIQ modules show improvements of 10 to 12 points or more, particularly in domains of symptom bother, social functioning, and emotional well-being. These findings are sustained in long-term follow-ups, often extending beyond 6–12 months of continuous therapy.

Notably, adherence rates are significantly higher compared to traditional PTNS, largely due to the automated delivery, convenience of home-based use, and reduced need for clinical follow-up. This shift toward user-independent therapy marks a critical step forward in achieving durable, scalable symptom control for a wide range of patients.

4. Future Vision: Adaptive Closed-Loop Neuromodulation

Sensor-Driven Feedback Systems

The next frontier in iTNS lies in the integration of real-time physiological sensing. Researchers and developers are working toward embedding MEMS-based sensors that monitor bladder pressure, detrusor muscle activity, or nerve conduction patterns. These inputs can inform real-time therapy adjustments, enabling closed-loop neuromodulation systems that respond instantly to bladder dynamics.

Artificial Intelligence and Personalization

AI-enhanced control algorithms will allow iTNS systems to learn from individual patterns and autonomously optimize stimulation. For instance, the system could increase intensity during high-risk times (e.g., early morning or before diuresis) or suppress therapy during inactivity, thereby improving both effectiveness and battery efficiency.

Benefits of Fully Adaptive Systems

Improved Efficacy: Therapy remains effective even as patient physiology or lifestyle changes.
Reduced Habituation: Dynamic variation in stimulation patterns prevents neural desensitization.
Lower Maintenance: Smart power management prolongs device life, reducing surgical revisions.
Precision Therapy: Stimulation is delivered only when needed, minimizing off-target effects.

These advancements will transition iTNS from a passive intervention to a proactive, intelligent medical platform, aligning with broader trends in digital and personalized medicine.

5. Conclusion

Implantable tibial nerve stimulation (iTNS) is a significant advancement in overactive bladder management, particularly for patients unresponsive to pharmacological or invasive treatments [4]. Through the integration of biomedical engineering, wireless power, and AI-driven feedback, modern iTNS systems are becoming more compact, automated, and intelligent.

With strong clinical outcomes and increasing regulatory support, iTNS is reshaping the landscape of urological care. The adoption of closed-loop designs and real-time personalization is driving the evolution toward truly adaptive neuromodulation offering safer, more sustainable, and patient-specific therapy. This progress highlights the vital role of engineering in bridging innovation with impactful, real-world clinical solutions.

6. Acknowledgements

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