Abstract #456 - Feasibility of Replacing the Tibial Nerve Neuromodulation Implant RENOVA iStim.

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Introduction and aim

Introduction

The RENOVA iStim System™ (BlueWind Medical, Park City, Utah, USA), is a minimal invasive treatment modality for lower urinary tract dysfunction. It is a form of tibial neuromodulation wherein an implantable electrode is powered using an external wearable stimulation unit. By doing so it eliminates the need for implanted batteries. However, given the limited space and anatomical constraints, removing the original implant and successfully positioning the subsequent implant in the same location with comparable clinical effectiveness could be a demanding task.

Aim

Through this report we explore the surgical, technical and clinical aspects of revision surgery of the RENOVA iStim System™. By elucidating the operative technique and sharing our clinical observations, we share insights into the practical application of tibial neuromodulation and the RENOVA iStim System™, especially with respect to implant replacement.

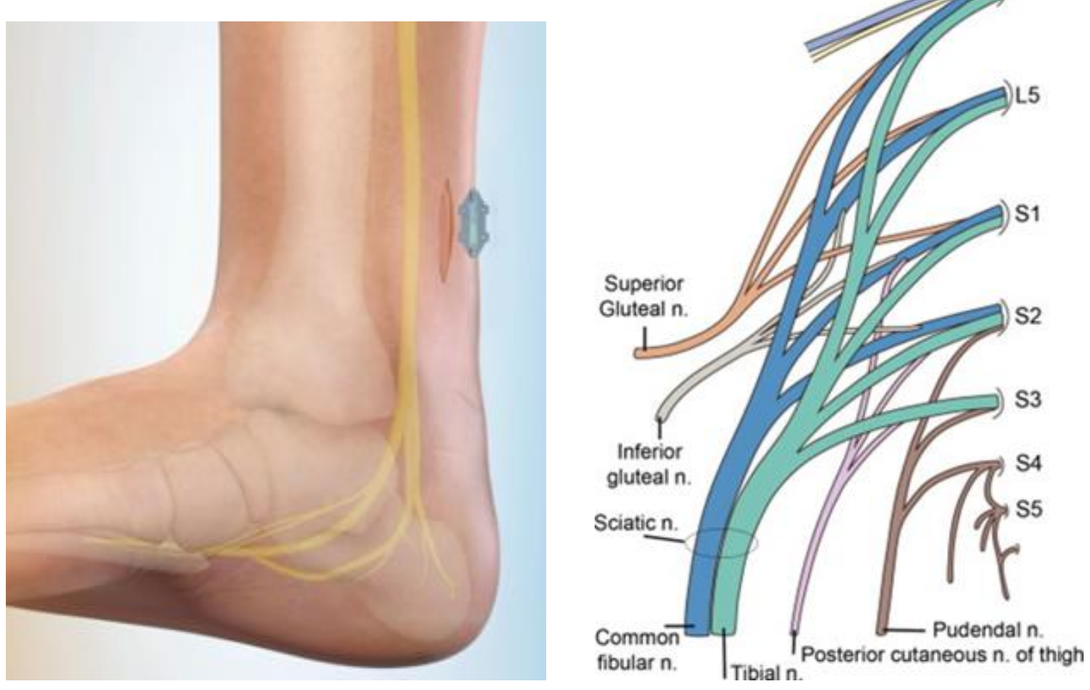

Figure 1. Implant location and Lumbosacral Plexus

Study design, materials and methods

Population

A cohort of patients received the RENOVA iStim System™ for overactive bladder (OAB) with urgency urinary incontinence (UUI) as part of a three-year follow up study. Due to an incompatibility between the old implant and the new generation wearable stimulation unit this cohort necessitated a revision of the implant.

Methods

The new implant was activated four weeks after revision surgery and an efficacy assessment was done at three months post-revision. During this assessment patients were asked to fill out a three day voiding diary, global satisfaction and postoperative complications were routinely checked. The voiding diaries were compared to data from the original study. After six month patient reported outcome was evaluated using a Patient Global Impression of Improvement (PGI-I) questionnaire.

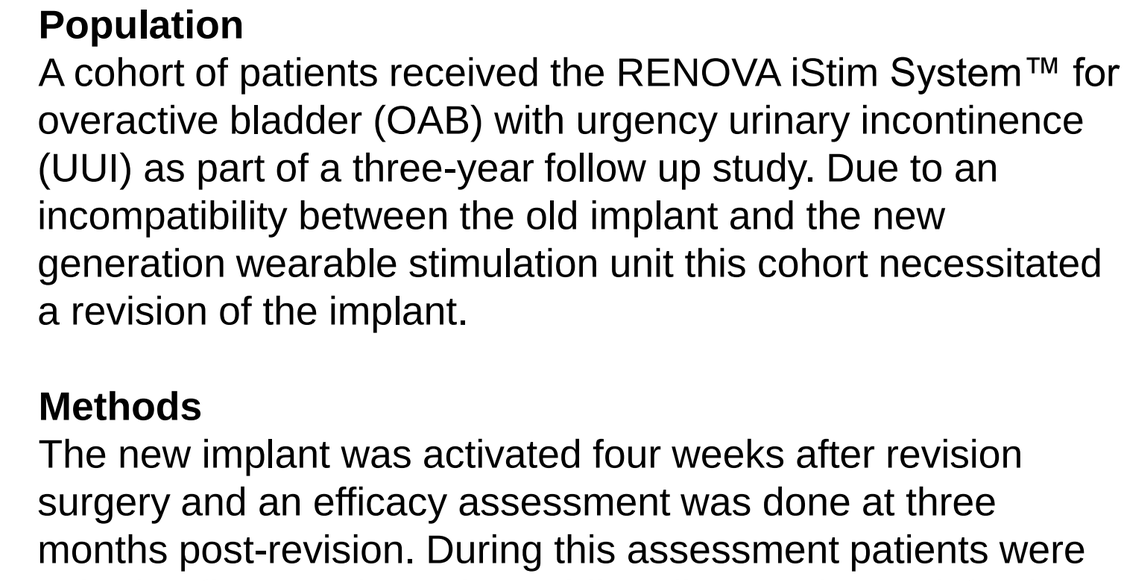

Figure 2. Left; Revi Wearable, Right; Revi Implant

Results and interpretation

Results

Five patients needed revision surgery due to the need of replacing the external wearable unit which was not compatible with the old implant. All patients suffered from OAB with UUI and received a first generation implant in 2015.

Surgical aspects

Revision surgery was performed in 2022. Surgically, the procedure was performed without difficulties and was well tolerated by patients under local anaesthesia. The mean operating time was 48 minutes and no complications occurred.

Clinical aspects

Clinically there was a sustained improvement compared to baseline voiding diaries and baseline is depicted in Table 1. The mean PGI-I score was 3 (SD 1.79). One patient was not satisfied with the results after three month and was successfully reprogrammed.

	Baseline	36 months FU	Post-revision
Leaks/day	7.67 (4.43)	1.27 (2.22)	3.13 (4.82)
Severity UUI	1.74 (0.37)	0.64 (0.44)	0.78 (0.84)
Frequency/day	11.07 (1.57)	9.00 (2.78)	8.40 (2.73)
Pads	2.47 (1.85)	0.53 (0.91)	0.21 (0.19)
Urge	5.87 (2.91)	2.53 (3.12)	3.53 (1.81)

Table 1: Voiding diary results. Stated as mean and SD.

Interpretation

- Revision surgery of the RENOVA iStim System™ is easily performable and well-tolerated under local anaesthesia.
- This cohort showed no peri- or postoperative complications demonstrating the safety of the procedure.
- The majority of the patients reported a sustained improvement in symptoms mainly in frequency and pads.
- The patient who was not satisfied restored efficacy after altering stimulation parameters. This highlights the programmability of the device after revision.
- These outcomes after revision surgery underscore the potential of the RENOVA iStim System™ as a long-term therapeutic option for patients with OAB with UUI, even after the need for implant revision arises.

Conclusion

The RENOVA iStim System™ is a promising therapeutic option in neuromodulation for overactive bladder. The revision procedure proved safe and easily performable together with restoring symptom relief and patient satisfaction.

References

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