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Expanding the Role of iTind®: First Clinical Experience in Treating Bladder Neck Contracture Following TURP

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1. Abstract

1.1. Background

To present the first documented cases of using the iTind® device as a novel, minimally invasive treatment for recurrent bladder neck contracture (BNC) following transurethral resection of the prostate (TURP), and to assess its feasibility, safety, and early outcomes.

1.2. Case Description

Two male patients with recurrent BNC, both of whom had undergone previous transurethral bladder neck incisions with limited or temporary benefit, were selected for off-label iTind® implantation. After obtaining informed consent, the device was deployed under sedation and removed after seven days as per standard protocol. Procedural steps included cystoscopic evaluation, sequential dilation of the bladder neck, and stent placement under direct vision. Both patients were followed up for 7–8 months with symptom scores, uroflowmetry, post-void residual assessments, and flexible cystoscopy to evaluate outcomes.

1.3. Conclusions

iTind® implantation resulted in significant symptomatic relief, improved urinary flow, and preserved sexual function in both patients without perioperative complications. As a non-thermal, day-case intervention, iTind® may offer a promising alternative to conventional BNC treatments, especially in recurrent cases. However, its use remains investigational in this setting, and larger prospective studies are needed to validate its long-term efficacy and safety.

2. Introduction

Bladder neck contracture (BNC) is a distressing complication that can occur following transurethral surgery for benign prostatic hyperplasia (BPH), with an incidence reported between 2% and 5%.[1] This condition significantly impacts patients' quality of life, as it reintroduces bladder outlet obstruction and voiding-predominant lower urinary tract symptoms (LUTS) after initial symptom relief. Despite various surgical interventions, recurrence remains a notable challenge in the management of BNC.

Conventional treatment options include serial dilatation, endoscopic bladder neck incision using various energy modalities, intralesional mitomycin C injection, and, in refractory cases, open surgical reconstruction of the bladder neck. Each approach carries its own limitations, risks, and complications including future recurrences, urethral stricture and sexual dysfunction postoperatively. These complications are particularly encountered due to the thermal-based nature of endoscopic procedures like bladder neck incision, which adds to the risk of further scarring and narrowing, comprising bladder neck integrity. Therefore, novel techniques need to be considered to allow effective treatment of BNC while reducing the risk of further contracture recurrence.

iTind® is a novel, temporarily implantable nitinol device designed to reshape the prostatic urethra and bladder neck through localized ischemic pressure (Figure 1). Following removal, the expanding nitinol struts create slits in the tissue, which expand to improve urinary flow through the bladder neck and prostatic channel. It is typically left in situ for approximately five to seven days and has been shown to improve urinary flow and symptoms in patients with BPH while preserving sexual function, with no impact on erection or ejaculation. To our knowledge, we report the first two documented cases in the literature where iTind® was utilized for the treatment of recurrent bladder neck contracture.

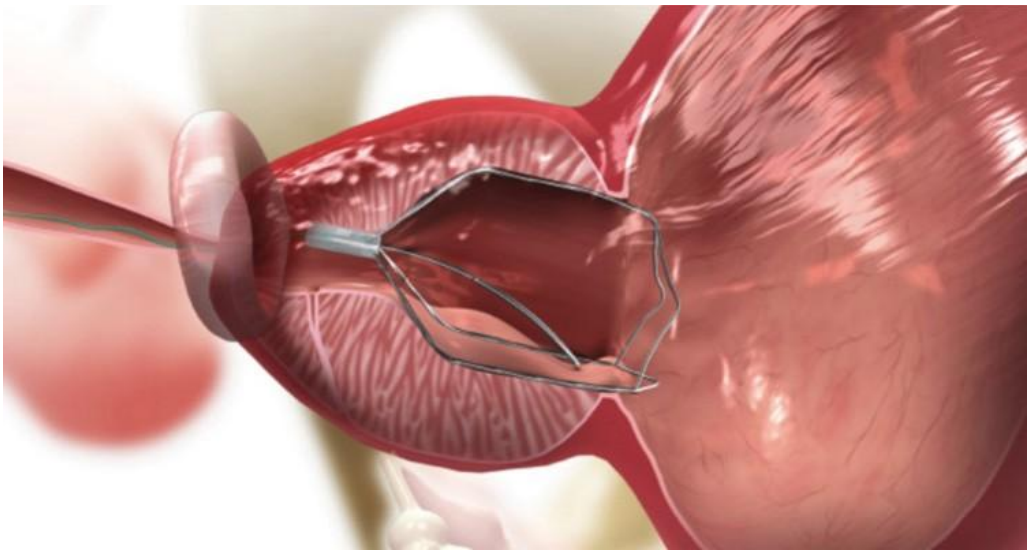

Figure 1: iTind® temporarily implantable nitinol device.

3. Case Presentation 1

A 51-year-old man presented with severe voiding-predominant lower urinary tract symptoms (LUTS). He had a history of trans-urethral resection of the prostate (TURP) performed at another hospital for the management of LUTS. However, within a few months, he developed BNC with significantly reduced urinary flow. He subsequently underwent two bladder neck incisions (BNIs) to relieve the contracture, but unfortunately, the BNC re-curred. His initial International Prostate Symptom Score (IPSS) was 35 and QoL 6.

After a thorough discussion of treatment options, including the off-label use of the iTind® (temporary implanted nitinol device) stent, the patient opted for iTind® placement. Written informed consent was obtained.

The procedure was performed under sedation and sterile conditions in the lithotomy position. A rigid cystoscope was introduced, revealing a normal urethra and a tight, nearly pinpoint bladder neck contracture (Figure 2). Blunt passage through the bladder neck was not possible; therefore, a guidewire was advanced into the bladder. Sequential dilation of the bladder neck was performed using S-shaped dilators up to 20 Fr. The cystoscope was then reinserted, allowing access to the bladder and completion of the cystoscopic examination.

The iTind® stent was then introduced through the cystoscope sheath and deployed under direct vision in a satisfactory position (Figure 3). The retrieval string was left in situ, and the standard protocol was followed, with stent removal performed one week later under local anaesthesia in a clinic setting.

At seven months postoperatively, the patient reported improved urinary symptoms with IPSS 11 and QoL 3, significantly improved urinary flow – Qmax of 18.5 mL/sec, and no significant post-void residual urine - 29 mL. Flexible cystoscopy at seven months postoperatively (Figure 4) – demonstrated a markedly improved bladder neck opening.

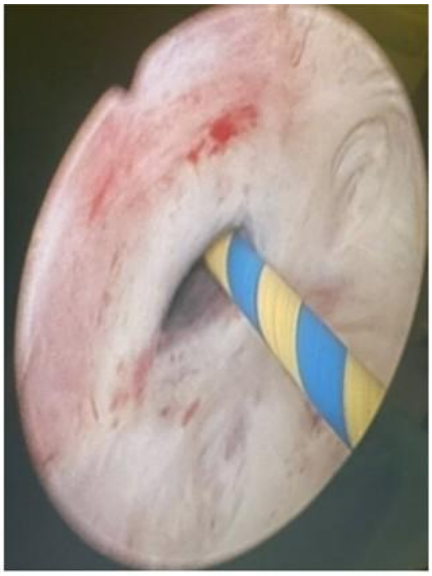

Figure 2: Pinpoint bladder neck contracture.

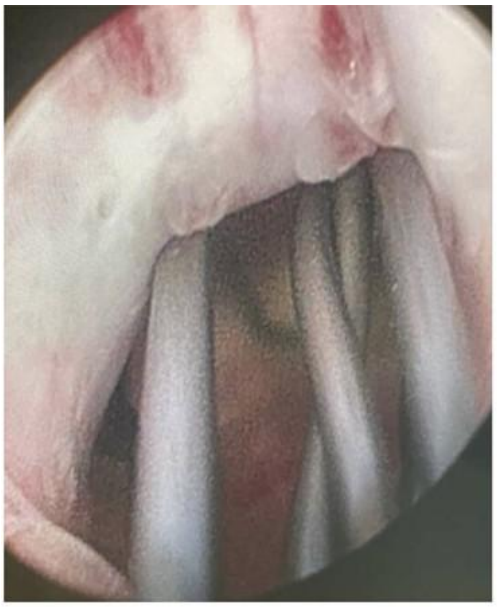

Figure 3: iTind placement to bladder neck.

Figure 4: Post iTind 7th month bladder neck.

4. Case Presentation 2

A 50-year-old man with a long-standing history (over 10 years) of urodynamically confirmed bladder outlet obstruction (BOO) presented with persistent voiding symptoms. He had previously undergone BNI in 2022 and a repeat BNI combined with limited TURP in 2023 at another hospital. However, like in the first case, he re-presented with worsening LUTS and poor urinary flow after some months. Again, BNC was diagnosed clinically.

Following a detailed discussion regarding management options, the patient elected to proceed with off-label placement of the iTind® stent for presumed bladder neck contracture. Written informed consent was obtained.

The procedure was carried out under sedation and sterile conditions in the lithotomy position. Rigid cystoscopy revealed a normal urethra but an impassable bladder neck contracture. A guidewire was advanced into the bladder, and the bladder neck was gradually dilated with S-shaped dilators up to 20 Fr.

The iTind® device was then deployed under direct vision in a satisfactory position. The retrieval string was left in situ, and the stent was removed uneventfully after one week according to the standard protocol described above. Following iTind® removal, the bladder neck was observed to be satisfactorily open (Figure 5). He has been under our routine follow-up for the past 8 months and has reported improved urinary flow.

Figure 5: Bladder neck after iTind removal.

5. Discussion

Surgical treatment for benign prostatic enlargement is a common urological procedure performed worldwide. Although rare, bladder neck contracture following transurethral resection of the prostate (TURP) or similar interventions can be a frustrating postoperative complication. It often requires repeat surgical interventions due to its high recurrence rate and the limited efficacy of current treatment modalities.

Several risk factors have been associated with an increased likelihood of BNC, including chronic kidney disease, cerebrovascular disease, multiple comorbidities (≥2), smaller prostate volume (<42.9 cm^3), and re-catheterization following initial surgery [2].

Standard therapeutic options for BNC include urethral dilatation, transurethral incision using electrocautery or laser, intralesional mitomycin C injection, and, in refractory cases, open surgical reconstruction. Since then, novel techniques have been employed to try to treat the recurrent BNC and a recent case report also described the successful use of a drug-coated balloon dilator (Optilume®) specifically for the treatment of bladder neck contracture [3].

iTind® is designed to apply pressure on the prostatic urethra and bladder neck via its expanding nitinol struts leading to ischaemic necrosis at those sites. Following removal of the stent seven days later, this ischaemic pressure translates into slits which when healed, facilitate improved urinary flow through a widened prostatic cavity and bladder neck. This non-thermal approach leads to better tissue remodeling and reduction in resistance to urinary flow while preserving ejaculation and erectile function [4]. The MT-06 study demonstrated significant improvement in peak urinary flow rate (Qmax), International Prostate Symptom Score (IPSS), and quality of life at six months, with all participants maintaining their baseline sexual function [5]. Additionally, a four-year follow-up study from Italy reported a 45% improvement in IPSS and sustained QoL benefits in patients treated with Tind® [6].

While iTind® has primarily been studied in the context of BPH-related LUTS, our application of the device in two cases of post-TURP bladder neck contracture suggests a potential new use for this minimally invasive therapy. In both patients, we observed symptomatic relief, improved urinary flow, and avoidance of further invasive procedures over the follow-up period. Given the morbidity associated with recurrent BNC and the limitations of existing treatments, these initial results are encouraging. Following our successful use of iTind® in these two BNC cases, we found iTind® to offer a simple, safe, and effective surgical approach with no significant post op complications and preserved sexual function. Both cases were performed under short sedation in a day-case setting, with same-day discharge and no postoperative catheterization. Our main hypothesis is that due to the non-thermal nature of the iTind® stent, the bladder neck integrity is more preserved than with conventional thermal-based BNI, which may lead to further scarring and narrowing.

Nevertheless, it is important to note that these findings are based on a limited number of cases. Larger studies are needed to establish the efficacy, safety, and long-term durability of iTind® in the management of post-surgical bladder neck contractures.

6. Conclusion

Our preliminary experience suggests that iTind® may offer a promising minimally invasive alternative for the treatment of bladder neck contracture following TURP. The device appears to provide symptomatic relief, improve flow rates, and delay or prevent the need for repeat surgical interventions-all while preserving sexual function. However, its use in this setting remains experimental, and robust prospective studies with larger patient populations are essential to validate its role in the treatment algorithm of BNC. If proven effective, iTind® could represent a significant advancement in the management of this challenging condition.

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