MT02 (12 months)

Second-generation of temporary implantable nitinol device for the relief of lower urinary tract symptoms due to benign prostatic hyperplasia: results of a prospective, multicenter study at 1 year of follow-up.

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Objective

To report the clinical experience with a second-generation of temporary implantable nitinol device (iTind; Medi-Tate Ltd, Or-Akiva) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) after 1 year of follow-up.

Patients and Methods

This multicenter, single-arm, prospective study evaluated the feasibility and safety of the second-generation temporary implantable nitinol device (iTind) in 81 patients.

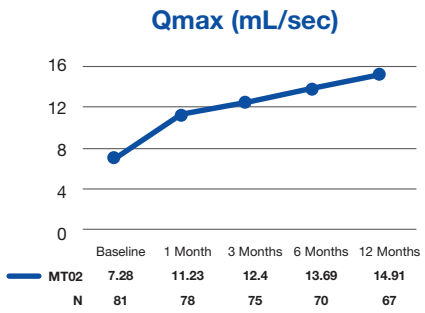
Inclusion Criteria:
· IPSS ≥ 10
· Qmax ≤ 12 mL/s
· Prostate volume < 75 mL

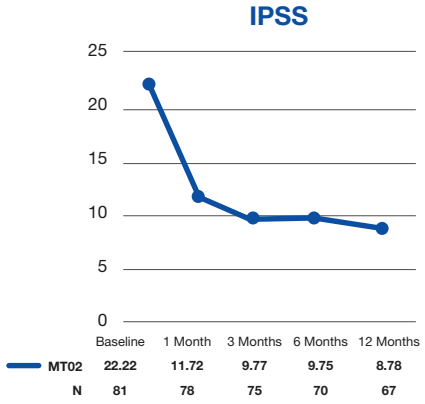
Exclusion Criteria:
· Haemostatic disorders
· PVR > 250 mL
· Obstructive median lobe
· Previous prostate surgery

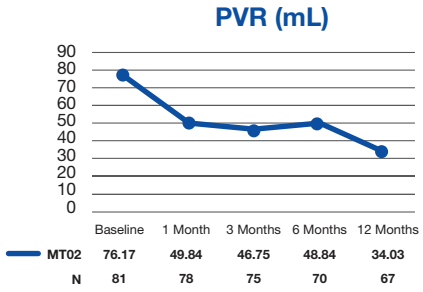
The iTind was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5-7 days later in an outpatient setting. Demographics, perioperative results, complications (according to the Clavien-Dindo system), functional results and quality of life (QoL) were evaluated. Follow-up assessments were conducted at 1, 3, 6 and 12 months postoperatively.

Results

The mean (SD) patient age was 65 (8.9) years and prostate volume was 40.5 (12.25) mL. At baseline, Qmax was 7.3 (2.6) mL/s, IPSS was 22.5 (5.6), and the median (interquartile range) IPSS QoL score was 4 (2–5). All the implantations were successful, with no intraoperative complications recorded; all patients were discharged on the same day of surgery. The devices were retrieved at a mean (SD) of 5.9 (1.1) days after implantation, typically under topical anesthesia. No Clavien–Dindo Grade >II complications were recorded. The mean (SD) Qmax at 1 month follow-up was 11.2 (5.7) mL/s and continued to improve thereafter, reaching 14.7 (8.1) mL/s at 12 month follow-up (+100%). The mean (SD) IPSS score was 11.7 (8.0) after 1 month and further improved to 8.8 (6.4) at 12 month follow-up (60%). In parallel, the mean (SD) IPSS QoL score drop reached 1.6 (1.3) by the end of the study. During the 12 month period, two patients (2.4%) required medical therapy for BPH, two patients (2.4%) required transurethral resection of the prostate, and 10 patients were lost to follow-up (12.3%). Compared to baseline, none of the 61 sexually active patients who completed the 12 month follow-up period reported sexual or ejaculatory dysfunction.







Adverse Events

Complication	%	Treatment
Hematuria	12.3%	Self-resolving
Urgency	11.1%	Self-resolving
Pain	9.9%	Oral analgesic
Dysuria	7.4%	Self-resolving
Urinary retention (immediately post-procedure)	9.9%	- Empty bladder with 12F catheter through device struts - Patient discharged without catheter

Conclusion

iTind implantation is feasible, safe and effective in providing relief of BPH-related symptoms for at least 1 year after treatment. Sexual and ejaculatory functions are fully preserved. Further studies with a longer follow-up period are needed to assess the durability of these results and to clearly define the indications for iTind implantation.

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