

MT01 (36 months)

3-Year follow-up of temporary implantable nitinol device implantation for the treatment of benign prostatic obstruction.

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Objective

To report 3-year follow-up results of the first implantations with a temporary implantable nitinol device (TIND; Medi-Tate Ltd., Or Akiva, Israel) for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Patients and Methods

This single-arm, prospective study evaluated the feasibility and safety of TIND implantation in 32 patients presenting with LUTS secondary to BPH.

Inclusion Criteria:

- Age \geq 50 years
- IPSS \geq 10
- Qmax \leq 12 mL/s
- Prostate Volume assessed by TRUS of $<$ 60 mL

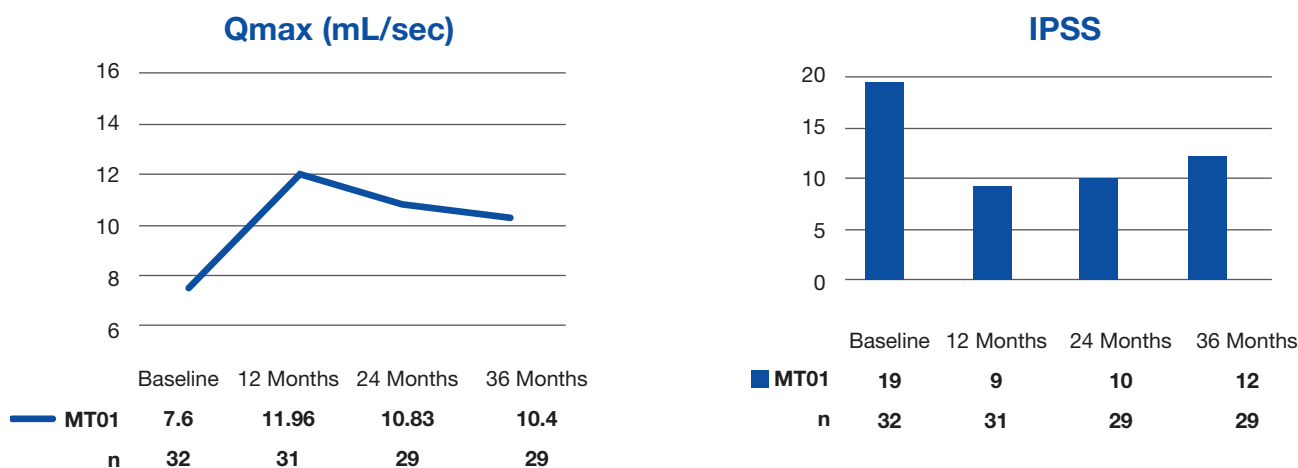
Exclusion Criteria:

- Prior prostate surgery
- Prostate cancer
- Urethral stricture
- Bladder stones
- Obstructing median lobe
- Haemostatic disorder
- Neurological conditions that could potentially affect voiding function

The TIND was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5 days later in an outpatient setting. Demographics, perioperative results, complications (according to Clavien–Dindo classification), functional results, and quality of life (QoL) were evaluated. Follow-up assessments were made at 3 and 6 weeks, and 3, 6, 12, 24 and 36 months after the implantation.

Results

At baseline, the mean (standard deviation, SD) patient age was 69.4 (8.2) years, prostate volume was 29.5 (7.4) mL, and Qmax was 7.6 (2.2) mL/s. The median (interquartile range, IQR) IPSS was 19 (14-23) and the QoL score was 3 (3-4). All the implantations were successful, with a mean total operative time of 5.8 min. No intraoperative complications were recorded. The change from baseline in IPSS, QoL score and Qmax was significant at every follow-up time point. After 36 months of follow-up, a 41% rise in Qmax was achieved (mean 10.1 mL/s), the median (IQR) IPSS was 12 (6-24) and the IPSS QoL was 2 (1-4). Four early complications (12.5%) were recorded, including one case of urinary retention (3.1%), one case of transient incontinence due to device displacement (3.1%), and two cases of infection (6.2%). No further complications were recorded during the 36-month follow-up.



Adverse Events

Complication	N	Result
Urinary incontinence	1 patient	- Caused by device displacement - Device was immediately removed — Patient reported no urine leakage
Urinary retention (AUR)	1 patient	- Bladder was voided using a catheter that was immediately removed - No further complications recorded with this patient
Urinary infection	2 patients	- Resolved after antibiotic therapy

Conclusion:

The extended follow-up period corroborated previous findings and suggests that TIND implantation is safe, effective and well-tolerated, for at least 36 months after treatment.

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