MT02 (36 months)

3-Year results following treatment with the second generation of the temporary implantable nitinol device in men with LUTS secondary to benign prostatic obstruction.

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https://pubmed.ncbi.nlm.nih.gov/33005003/

Objective

To report the 3-year results of a prospective, single-arm, multicenter, international clinical study with the second generation of the temporary implantable nitinol device (iTind; Medi-Tate Ltd®, Israel) on men suffering lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

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

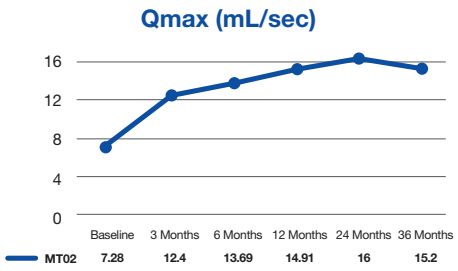
Exclusion Criteria:
· PVR > 250 mL
· Obstructive median lobe
· Previous prostate surgery
· Confounding bladder or sphincter dysfunction
· Active urinary infection
· Unable to interrupt antithrombotic or antiplatelet treatment

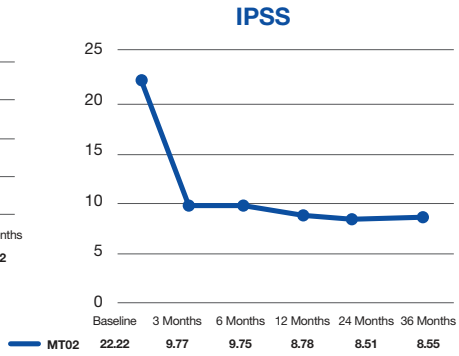
A wash-out period of 1 month for alpha-blockers and 6 months for 5-ARIs was mandatory to avoid confounders. The iTind was implanted within the bladder neck and the prostatic urethra under light sedation, using a rigid cystoscope. The device was removed 5-7 days later in an outpatient setting. Demographics, 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, 12, 24 and 36 months postoperatively.

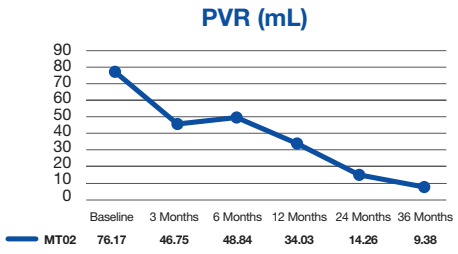
Results

Of the 81 patients initially enrolled, follow-up included 50 men at 3 years. For the 50 men included in the present analysis, the median age was 62.79 years and median prostate volume was 37 mL (range 16-65 mL). At 36 month follow-up, IPSS decreased from baseline by 58.2%, QoL by 55.6% and PVR by 84.5%, and Qmax improved by 114.7% (all significantly different from their corresponding baseline values, $p<0.0001$).

Even considering intention to treat (ITT) analysis, 36-month results demonstrate significant improvement in functional outcomes compared to baseline values (all $p<0.0001$). No late post-operative complications were observed between 12 and 36 months. Sexual functional was stable through 3 years, with no reports of sexual or ejaculatory dysfunction according to two yes/no questions over the follow-up period. Between 12 and 24 months follow-up, 5 patients underwent surgery. Further investigation revealed that four of the five patients had median lobes and were protocol deviators. Failure analysis identified median lobe as a strong predictor of iTind treatment failure, with 58.33% ($p < 0.0001$) of patients in the failure group (7 out of 12) had median lobes. No other preoperative variables (age, prostate volume, IPSS scores, Qmax, PVR, PSA) were found to predict response to iTind treatment. Between 24 and 36 months follow-up, no patients underwent alternative treatments.







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 12 Fr catheter through device struts - Patient discharged without catheter

Conclusion

Treatment of LUTS secondary to BPH with iTind demonstrated a significant, durable reduction in symptoms and improvement of functional parameters and quality of life at 3 year follow-up. No late post-operative complications, ejaculatory dysfunction or additional treatment failures were observed between 24 and 36 months.

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